

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING,  
SALES PRACTICES, AND PRODUCTS  
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-  
2738-FLW-LHG**

**MDL No. 2738**

***THIS DOCUMENT RELATES TO ALL  
CASES***

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**THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN  
RESPONSE AND OPPOSITION TO JOHNSON & JOHNSON AND  
JOHNSON & JOHNSON CONSUMER INC.'S MOTION TO EXCLUDE  
PLAINTIFFS' EXPERTS' ASBESTOS-RELATED OPINIONS**

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## I. INTRODUCTION

Under any measure, the presence of asbestos in Johnson & Johnson's Talcum Powder Products poses a serious threat to the American women who have used those products for decades. Even Johnson & Johnson ("J&J") has been forced to acknowledge this common-sense notion, bowing to the unassailable fact derived from decades of research that asbestos is extremely harmful, and to the reality that it is too often fatal. As J&J's corporate representative Susan Nicholson put it, "I would not support Johnson & Johnson selling a product that contained asbestos," because "it would be wrong".<sup>1</sup>

Regrettably, in its Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions,<sup>2</sup> J&J resorts to unsupported distinctions in terminology and blind indifference to the facts and the science that support the PSC's experts' opinions. This Court should reject J&J's arguments for the reasons that follow.

First, in an effort to avoid liability and cast doubt on the PSC's experts' opinions, J&J attempts to re-imagine standard, scientifically accepted definitions of

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<sup>1</sup> See July 26, 2018 Deposition of Susan Nicholson (J&J's 30(b)(6) witness for safety) at 34:10-35:5; 48:14-49:14, attached hereto as **Exhibit 1**; November 16, 2018 Expert Report of Mark Krekeler, Ph.D. ("Krekeler Report") at 7, attached hereto as **Exhibit 2**.

<sup>2</sup> Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Memorandum of Law in Support of Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions (ECF. Dkt. No. 9736-3) (referred to herein as "J&J's Mem." or "Def. Mem.") The underlying motion will be referred to as "J&J's motion."

asbestos fibers set by industry regulators—while falsely accusing the PSC’s experts of re-defining “asbestos.” The Court should not fall for this ruse. The Environmental Protection Agency has rejected J&J’s precise argument, finding that there is no supportable distinction between “asbestos” and so-called “cleavage fragments.” This conclusion is fatal to J&J’s entire motion.

Second, J&J spends dozens of pages criticizing Drs. William Longo and Mark Rigler’s methodology, largely by insisting on the false distinction regarding cleavage fragments described above and by attempting to add requirements that are not included in relevant industry standards. The PSC’s experts fully followed relevant scientific testing methodologies that have been adopted by the broader scientific community. J&J’s criticisms are unavailing.

Third, the scientific literature fully supports a correlation between asbestos exposure and ovarian cancer. This correlation is not reasonably debatable.

Finally, the overwhelming weight of the evidence in this case supports the conclusion that the talc deposits in Italy, Vermont, and China utilized by J&J for its Talcum Powder Products were contaminated by asbestos. This conclusion flows from both the scientific literature and J&J and Imerys Talc America’s (“Imerys”) own documents. In this regard, the PSC’s experts’ opinions are consistent with J&J’s own testing.

For all these reasons, the Court should deny J&J’s motion.

## **II. BACKGROUND**

As background, this Court should be aware that (1) scientific literature and documents produced by both J&J and Imerys in this litigation fully establish the presence of asbestos in the talc mines from which J&J obtained its raw materials; (2) contrary to J&J's assertions, the scientific literature fully supports the association between asbestos and ovarian cancer; and (3) the very experts whose testimony J&J seeks to exclude have been permitted to testify concerning the issues presented in this case in courts around the country.

### **A. The Scientific Literature and J&J's and its Suppliers' own documents fully establish the presence of asbestos in the mines and materials used in J&J Talcum Powder Products**

From 1926 through the present, J&J sourced talc for its Talcum Powder Products from three main regions: Italy's Chisone Valley district (1926-1970s),<sup>3</sup> Vermont (mid-1960s to 2003),<sup>4</sup> and the Guangxi province of China (2003 to present). These talc deposits contain as a natural part of their geologic formation varying concentrations of platy talc, fibrous talc (or talc formed in an asbestiform

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<sup>3</sup> Talc sourced from the Fontane Mine in the Val Chisone Valley in Italy was designated after beneficiation as EGAT EXTRA 00000 or 1615 AGIT. *See* January 22, 2019 Amended Rule 26 Expert Report of Robert B. Cook, Ph.D. ("Cook Report") at 4, attached hereto as **Exhibit 3**; Krekeler Report at 7-8 (citing IMERYS 077321, IMERYS 334779 and IMERYS 117598), attached hereto as **Exhibits 4, 5, and 6**.

<sup>4</sup> Talc sourced from the Vermont Mines (Johnson, Hammondsville, Hamm, Black Bear, and Argonaut mines) was referred to after beneficiation as Grade 66. *See* Amended Cook Report at 5.

habit), asbestos (both serpentine and amphiboles),<sup>5</sup> and heavy metals such as nickel, chromium, and cobalt.<sup>6</sup> The evidence for the presence of these constituents arises from three sources: 1) published literature; 2) historical tests memorialized in corporate documents; and 3) the testing of historical samples by Drs. Longo and Rigler.

**1. Published literature describing the mineralogy of the regions from which J&J sourced its talc provides evidence that the mines contain asbestos and fibrous talc**

An understanding of the regional geology where the talc was mined is important in order to evaluate the unique features of individual mineral deposits. Although the individual conditions and contents of a talc deposit must be assessed, the specific mineral occurrence does not happen in a vacuum but in the context of

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<sup>5</sup> Asbestos is the generic designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series.

Mineral Group	Mineral Type
Serpentine	Chrysotile
Amphibole	Actinolite, Amosite, Anthophyllite, Crocidolite, Tremolite

See International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, Volume 100C. Arsenic, metals, fibres, and dusts. Lyon, France: IARC; 2012 (hereinafter referred to as IARC, 2012), attached hereto as **Exhibit 7**.

<sup>6</sup> The evidence relating to the presence of heavy metals will be set forth in the *Plaintiffs' Steering Committee's Response and Opposition to Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower-to-Shower*.

the regional geology. The geologic features of the locations from which J&J sourced its Talcum Powder Products are such that the presence of asbestos and fibrous talc is an expected occurrence.

Talc is a soft magnesium silicate mineral with the formula  $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$ . “Talc particles are normally plate-like . . . [but] may also form true mineral fibers that are asbestiform in habit.”<sup>7</sup> Talc is formed through the alteration of two types of pre-existing rocks: dolomitic carbonates (as in Italy and China), or ultramafic rocks (as in Vermont). These pre-existing rocks have their own characteristic composition and associated constituents, as do the minerals derived from them.

Talc and serpentinites (including chrysotile asbestos) are both natural alteration products from the same pre-existing ultramafic rock, and they are commonly found in close proximity. Talc is also a product of the metamorphosis of amphiboles, a mineral species which includes several types of asbestos (including tremolite, actinolite and anthophyllite). The alteration process is not always completed as the temperature and pressure change, leaving a mixture of talc and serpentinites and/or amphiboles, or even transition particles which retain the

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<sup>7</sup> IARC, 2012 at 230.

characteristics of both minerals.<sup>8</sup> Thus, by virtue of the manner in which talc is formed, geologically it is commonly associated with asbestos minerals.

Italian talc deposits located in the Val Chisone Valley where J&J talc was sourced, were derived from carbonate rock and have been shown to contain accessory minerals such as asbestos (asbestiform tremolite and actinolite) and chlorite minerals.<sup>9</sup> The presence of asbestos in these Italian talc deposits is described in a 1990 publication by Marconi and Verdel.<sup>10</sup> In 2009, a report from an Imerys Talc America, Inc. predecessor company (Luzenac) described the accessory minerals of the Val Chisone talc deposits to include actinolite-tremolite, quartz, anthophyllite, and serpentine family minerals.<sup>11</sup>

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<sup>8</sup> Van Gosen BS, Lowers HA, Sutley SJ, Gent CA. 2004. Using the geologic setting of talc deposits as an indicator of amphibole asbestos content. *Environmental Geology*. 45(7):920-939, attached hereto as **Exhibit 8**; Virta, Robert L. The Phase Relationship of Talc and Amphiboles in a Fibrous Talc Sample” Bureau of Mines Report of Investigations (1985), attached hereto at **Exhibit 9**.

<sup>9</sup> Krekeler Report at 9, citing IMERYS 245144, attached hereto as **Exhibit 10**; IMERYS 467511, attached hereto as **Exhibit 11**; IMERYS-A\_0024548, attached hereto as **Exhibit 12**; JNJ 000521616, attached hereto as **Exhibit 13**; JNJAZ55\_000006341, attached hereto as **Exhibit 14**; JNJMX68\_000017827, attached hereto as **Exhibit 15**; WCD\_002478, attached hereto as **Exhibit 16**.

<sup>10</sup> Marconi A, Verdel U. 1990. Asbestos content of talcs from Italian mines and fibre concentration in various commercial talcum powders used in Italy. In: Bignon J. (eds) *Health Related Effects of Phyllosilicates*. NATO ASI Series (Series G: Ecological Sciences), Vol. 21. Springer, Berlin, Heidelberg, attached hereto as **Exhibit 17**.

<sup>11</sup> See August 7, 2018 Deposition of Patrick Downey, an Imerys corporate representative (“Downey Dep.”) attached hereto as **Exhibit 18**.

The Vermont deposits that sourced J&J's Talcum Powder Products from 1963 to early 2003 were derived from altered ultramafic rocks or serpentinites.<sup>12</sup> The Vermont talc source mines were the Johnson, Hammondsville, Hamm, Rainbow, and Argonaut mines.<sup>13</sup> J&J owned the mines through its subsidiary, Windsor Minerals, Inc., from the mid-1960s until 1989. The Vermont mines and processing facilities were purchased from J&J by Cyprus Minerals and later acquired by Imerys Talc America, Inc.<sup>14</sup> In addition to sourcing talc for cosmetic products, these mines were also used to source industrial products.

The first comprehensive description of the Vermont talc deposits was written by A.H. Chidester in 1951,<sup>15</sup> with another analysis by Charles A. Ratté being published in 1982. These analyses of the regional geology of Vermont talc deposits describe the ultramafic origin of the talc and the association of serpentine-derived talc and asbestos deposits.<sup>16</sup> The asbestos minerals that occur in these talc-bearing

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<sup>12</sup> See Amended Cook Report at 4; *see also* "Krekeler Report" at 4-5.

<sup>13</sup> See Amended Cook Report at 5.

<sup>14</sup> Downey Dep. at 132:8-22.

<sup>15</sup> Chidester AH, Billings MP, and Cady WM. 1951. Talc Investigations in Vermont-Preliminary Report. U.S. Geological Survey Circular, Series No. 95, attached hereto as **Exhibit 19**.

<sup>16</sup> Ratté Charles A. 1982. Mineral Resource Provinces of Vermont. Vermont Geological Survey, DEC, attached hereto as **Exhibit 20**; *see also* Bain GW. 1934. Serpentinization, origin of certain asbestos, talc and soapstone deposits. *Economic Geology*. 29(4):397-400, attached hereto as **Exhibit 21**; Bain GW. 1942. Vermont talc and asbestos deposits. In Newhouse, W. H., ed., Ore deposits as related to

serpentinites include tremolite, actinolite, anthophyllite, and chrysotile.<sup>17</sup> These types of geologic analyses of Vermont talc deposits were previously reported in the 1991 published work of Dr. Alice Blount, a Professor of Geology at Rutgers University. Dr. Blount tested talcum powder sourced from Vermont and found that it contained asbestos.<sup>18</sup> Dr. Blount testified that the Vermont talc that she tested was actually J&J Baby Powder that she purchased off of the shelf in New Jersey.<sup>19</sup>

In addition to chrysotile and amphibole asbestos, the Vermont deposits also contain fibrous talc.<sup>20</sup> During the metamorphic process, amphiboles undergo

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structural features. Princeton University Press, 255 – 258, attached hereto as **Exhibit 22**; *see also* Van Gosen (2004).

<sup>17</sup> *See* Van Gosen (2004).

<sup>18</sup> Blount, AM. 1991. Amphibole Content of Cosmetic and Pharmaceutical Talcs. *Environmental Health Perspectives*. 94:225-230, attached hereto as **Exhibit 23**.

<sup>19</sup> *See* J&J 220, attached hereto as **Exhibit 24**; *see also* April 13, 2018 Deposition of Alice M. Blount, Ph.D., *Ingham v. Johnson & Johnson, et al.* at 10, 25, 30, attached hereto as **Exhibit 25**.

<sup>20</sup> In 1987, IARC evaluated the carcinogenicity of talc and concluded that there was sufficient evidence that talc containing asbestiform fibers was carcinogenic to humans. IARC Monograph on Silica and Some Silicates (1987), relevant excerpts attached hereto as **Exhibit 26**; IARC Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, Supplement (1987), relevant excerpts attached hereto as **Exhibit 27**. To clarify terminology, IARC (2010) stated that “[t]he term ‘asbestiform fibre’ has been mistaken as a synonym for ‘asbestos fibre’ when it should be understood to mean any mineral, including talc, when it grows in an asbestiform habit.” IARC Monograph on Carbon Black, Titanium Dioxide, and Talc, Volume 93 (2010) at 39 (emphasis supplied), relevant excerpts attached hereto as **Exhibit 28**. It re-addressed the issue of carcinogenicity: “The present Working Group also decided to expand the name of the Group-1 agent from ‘talc containing asbestiform fibres’ to ‘talc containing asbestos or other asbestiform

incomplete alteration to form transition fibers, composed of both fibrous talc and amphibole or serpentine.<sup>21</sup> When talc occurs in this form, it is considered to be in a fibrous form, or occurring in an asbestiform habit. Testing of samples from the Vermont mines done by Colorado School of Mines Research Institute in 1973 (and commissioned by J&J) showed that chrysotile asbestos, a component of the local Vermont serpentinite was altered in certain instances during the metamorphic process to form a fiber-like talc pseudomorph or fibrous talc.<sup>22</sup> Additional support for the formation of fibrous talc in Vermont deposits may be found in published

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fibres.’ *Id.* IARC, 2012 states that “the conclusions reached...about asbestos and its carcinogenic risks apply to these six types of fibres [chrysotile, actinolite, amosite, anthophyllite, crocidolite, and tremolite] wherever they are found, and that includes *talc containing asbestiform fibres*.” IARC, 2012 at 219 (emphasis added). It further differentiates the types of talc, indicating that “[t]alc may also form true mineral fibres that are asbestiform in habit.” IARC, 2012 at 230.

<sup>21</sup> See Van Gosen (2004).

<sup>22</sup> See Amended Cook Report at 28; see also See Chidester, AH. 1968. Evolution of the Ultramafic Complexes of Northeastern New England: Studies in Appalachian Geology, Chapter 26, John Wiley Interscience Publishers, New York, at 35, attached hereto as **Exhibit 29**.

articles by Ross (1968),<sup>23</sup> Stemple (1960),<sup>24</sup> and Virta (1985),<sup>25</sup> which describe the pseudomorphism of asbestiform tremolite or anthophyllite into fibrous talc.

Talc for J&J's Talcum Powder Products is presently sourced from the Jizhua Mine in the Guangxi Province of China. The talc deposit was derived from the alteration of dolomitic carbonate rocks.<sup>26</sup> Chinese talc deposits are not as well characterized mineralogically in the literature, and specific mine documents such as drill core logs and drill core testing data, blast-hole testing data, mine planning documents and mine maps have not been produced. However, a publication by Yuya Li, entitled "Discussion of the Genesis of Longsheng Talc Mine in Guangxi Province," describes the talc deposit as occurring in the setting of dolomite marble and spilite.<sup>27</sup> According to Li, spilite remains at a percentage of 8.14% on average

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<sup>23</sup> See Ross M, Smith WL, and Ashton WH. 1968. Triclinic Talc and Associated Amphiboles from Gouverneur Mining District, New York. *The American Mineralogist*. 53(5-6):751-769, attached hereto as **Exhibit 30**.

<sup>24</sup> See Stemple IS, Brindley GW. 1960. A Structural Study of Talc and Talc-Tremolite Relations. *Journal of the American Ceramic Society*. Vol. 43, No. 1, attached hereto as **Exhibit 31**.

<sup>25</sup> See Virta (1985).

<sup>26</sup> See Amended Cook Report at 4.

<sup>27</sup> Li, Yuya. 1979. Discussion on the Genesis of Longsheng Talc Mine in Guangxi Province. China National Exploration Center of Building Materials Industry, Guangxi Geological Team. (English translation of original Chinese publication); attached hereto at **Exhibit 32**.

within the talc ore deposit and the “content of tremolite in spilite is 30-35%.”

Tremolite is a member of the amphibole species of asbestos.

The published geological literature makes it clear that the mines from which J&J’s Talcum Powder Products were sourced contain asbestos and fibrous talc.

**2. Documents produced by J&J and Imerys Talc America, Inc. in this litigation demonstrate that the mines that sourced J&J’s talc and the Talcum Powder Products themselves contain asbestos and fibrous talc**

J&J’s own documents make clear that the deposits from which it sourced the talc for the Talcum Powder Products contained asbestos. Since at least the late 1950s, J&J has been in possession of geological analyses and test results evidencing the presence of asbestos in talc ore used to source J&J’s Talcum Powder Products as well as in the finished products. Notably, in analyses performed by the Battelle Memorial Institute, dated May 28, 1958, tremolite and up to 10% fibrous talc was found in Italian talc ores.<sup>28</sup>

In 1970, J&J commissioned the Colorado School of Mines Research Institute to evaluate the geology and ore reserves of the Hammondsville mine. A comprehensive report was compiled which documented the presence of actinolite

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<sup>28</sup> See Exhibit 28 to Deposition of John Hopkins, Ph.D., attached hereto as **Exhibit 33**; J&J 2, attached hereto as **Exhibit 34**.

and tremolite in the mine.<sup>29</sup> A report in 1991 stated that: “Fibrous minerals - tremolite and actinolite are ubiquitous in several zones of the Vermont mines.”<sup>30</sup>

A 1991 analysis of samples taken from core drilling in the Hamm mine in Vermont stated, “Fibrous actinolite was seen in chloritic dikes and occasionally extended a few inches into the talc ore at contacts.”<sup>31</sup> “Every hole encountered at least one chloritized mafic dike containing actinolite.”<sup>32</sup> Additional core drilling was done in 1992 at the Hamm mine which identified fibrous tremolite.<sup>33</sup> The Argonaut mine in Vermont was described as containing “actinolite with chlorite cinders and serpentinite.”<sup>34</sup> In 1992, R.C. Munro prepared an analysis of the Vermont talc deposits, writing that a “serious mineralogical contaminant in the talc ores of Vermont is fibrous variety of the amphibole minerals, tremolite and actinolite (hydrous calcium iron-magnesium silicates) which have been classified as asbestiform minerals by OSHA and EPA.”<sup>35</sup>

**a. The testing results in J&J’s possession further demonstrate the presence of asbestos at J&J’s source mines**

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<sup>29</sup> See JNJ 000245002, at 104-105 and 114-115, attached hereto as **Exhibit 35**.

<sup>30</sup> See IMERYYS 425354 at 355, attached hereto as **Exhibit 36**.

<sup>31</sup> See IMERYYS 238270 at 273, attached hereto as **Exhibit 37**.

<sup>32</sup> *Id.* at 276.

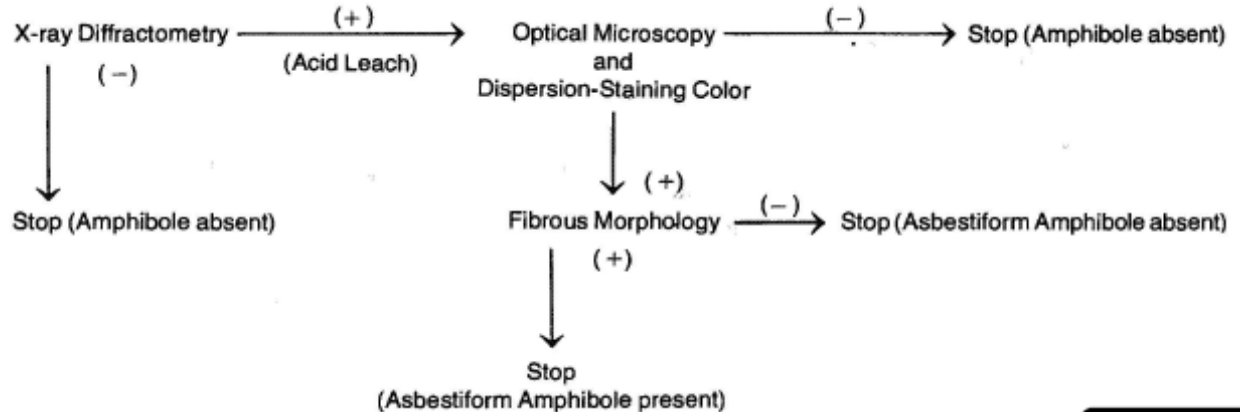
<sup>33</sup> IMERYYS 435992 at 994, attached hereto as **Exhibit 38**.

<sup>34</sup> IMERYYS 427291, attached hereto as **Exhibit 39**.

<sup>35</sup> IMERSY 219720, attached hereto as **Exhibit 40**.

Over the course of more than fifty years, J&J was aware of numerous positive test results confirming the presence of asbestos and fibrous minerals in its source mines. The tests were conducted on both ore *and* finished Talcum Powder Products.

The testing methods used—i.e., the J4-1 method—will be discussed in relation to Drs. Longo and Rigler’s testing, but it should be understood that the J4-1 method is a phased procedure with the initial step involving X-ray diffraction (XRD). Only if a test is positive by XRD would the sample be examined by the next step in the protocol, polarized light microscopy (PLM). If positive, the sample would then be examined under transmission electron microscopy (TEM).<sup>36</sup> A depiction of the J4-1 method is as follows:<sup>37</sup>



<sup>36</sup> See January 3, 1974 Johnson & Johnson memo from A. J. Goudie, JNJMX68\_000017515, attached hereto as **Exhibit 41**.

<sup>37</sup> See JNJNL61\_000106449 (“D-7131”), October 7, 1976 CTFA Method J-41, attached hereto as **Exhibit 42**.

Since at least the 1970s, J&J has acknowledged that “there seems to be general agreement that Transmission Electron Microscopy is the only absolute proof with electron diffraction for the identification of asbestos in talc.”<sup>38</sup> On the other hand, XRD—the only test performed on all samples—is wholly inadequate and does not test for chrysotile asbestos. Moreover, as explained further, the samples that were tested were not concentrated as recommended. Therefore, the detection limit of the testing was quite high – 0.5% and above. Positive test results should be evaluated in light of this high threshold. A “negative” test could have up to 0.5% asbestos and the results would be reported “not detected.”<sup>39</sup> *Johnson & Johnson admits that a negative test does not mean that the product is asbestos free.*<sup>40</sup>

In addition to focusing on the testing methods used, it is important to explain the frequency of historical testing. Asbestos testing at the mines was conducted on only **one sample on a quarterly basis**.<sup>41</sup> The testing was performed on a composite sample. The samples were created by taking a few ounces of ore from each multi-

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<sup>38</sup> See J&J employee A.J. Goudie Memorandum, dated January 3, 1974).

<sup>39</sup> See Amended Cook Rpt. at 40-41.

<sup>40</sup> See June 28, 2018 Deposition of Donald Hicks (J&J 30(b)(6) Corp. Rep.) (“Hicks Dep.”) at 143:23-146:11, attached hereto as **Exhibit 43**.

<sup>41</sup> See September 13, 2018 Deposition of Julie Pier (Imerys 30(b)(6) Corp. Rep.) (“Pier Dep.”) at 401:3-21, attached hereto as **Exhibit 44**; see also *id.* at 573:10-21 (Ms. Pier testifying that there in 2004 there was a backlog of samples of more than two years going back to 2001).

ton lot produced during a quarter, combining that material, and then testing a small aliquot of the composite sample. Importantly, the talcum powder was not quarantined while the sample was being processed, but the material was allowed to proceed to bottling and the shelves of stores without any process in place to hold the product while testing was performed.<sup>42</sup>

For purposes of TEM testing, the amount of talcum powder analyzed is approximately .001 gram or 10 millionth of a gram.<sup>43</sup> Assuming that J&J and Imerys conducted quarterly tests each year for the last fifty years, the amount of J&J talc examined by TEM would be **far less than 1 gram**. To put that in perspective, J&J and Imerys tested talcum powder in an amount equivalent to the weight of a paper clip, all the while selling literally thousands of tons of J&J Baby Powder and Shower to Shower from the same lot while the test proceeded.

A summary of the charts of positive asbestos test results identified by J&J or third-party labs acting on its behalf follows.<sup>44</sup> The chart includes the results of positive tests from the 1950s, 1960s, 1970s, 1980s, 1990s and 2000s.<sup>45</sup>

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<sup>42</sup> See Hicks Dep. at 94:4-95:5.

<sup>43</sup> *Ingham, et al. v. Johnson & Johnson, et al.*, Tr. 5326 (June 6, 2018) (testimony of John Hopkins, J&J corporate representative), attached hereto as **Exhibit 45**.

<sup>44</sup> Amended Cook Report at 13-21; Krekeler Report at 14-23.

<sup>45</sup> The majority of the results reported in the tables in the Cook and Krekeler reports are composed of the results contained in Exhibit 28 to the Johnson & Johnson 30(b)(6) deposition that was taken in the MDL. During the depositions of Johnson

Decade	Number of Positive Tests	Source	Types of Asbestos Found
1950s	5 <sup>46</sup>	Italy	Tremolite
1960s	1 <sup>47</sup>	Vermont	Altered amphiboles
1970s	47 <sup>48</sup>	Vermont	Tremolite Chrysotile Anthophyllite Actinolite Amphibole – needles & bundles Antigorite
1980s	15 <sup>49</sup>	Vermont	Massive amphiboles Chrysotile Anthophyllite Tremolite-actinolite

& Johnson, John Hopkins, PhD, was asked on behalf of the company about each of the tests outlined in a chart which eventually became Hopkins Exhibit 28. Dr. Hopkins agreed to the test results as recorded in the chart.

<sup>46</sup> See J&J 309; J&J 310; J&J 1; J&J 311, attached hereto as **Exhibit 46**.

<sup>47</sup> See J&J-313, attached hereto as **Exhibit 47**.

<sup>48</sup> See J&J-9; J&J-257; J&J-255; J&J-256; J&J-15; J&J-19; J&J-23; J&J-28; J&J-342; J&J-373; J&J-29; J&J-348; D-7; J&J-36, J&J-34, J&J-37; J&J-263; J&J-33; J&J-100; J&J-296; J&J-44; J&J-335; J&J-367; J&J-368; J&J-47; J&J-299; J&J-258; J&J-263; J&J-57; J&J-58; J&J-65; J&J-66; J&J-366; J&J-370; J&J-74; J&J-75; J&J-89; J&J-92; J&J-297; J&J-97; IMERYS210810; J&J-303; J&J-141; J&J-246; IMERYS210707; J&J-164; J&J-341, attached hereto as **Exhibit 48**.

<sup>49</sup> See IMERYS 210707; J&J-169; J&J-175; J&J-305; J&J-179; J&J-177; JNJMX86\_000013019; J&J-182; J&J-184; J&J-185; JNJ 000062176; J&J-190; J&J 0144301; JNJNL61\_000006792; JNJ 000223449, attached hereto as **Exhibit 49**.

			Tremolite Actinolite
1990s	17 <sup>50</sup>	Vermont	Chrysotile Antigorite Anthophyllite Actinolite Tremolite Actinolite Fibrous amphiboles
2000-2006	11 <sup>51</sup>	Vermont	Chrysotile Tremolite Anthophyllite Actinolite Tremolite

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<sup>50</sup> See J&J-0007797; J&J-0007801; JOJO-MA90013-0005; J&J 0007797; IMERYS 238478; IMERYS 238468; IMERYS 238457; IMERYS 211157; J&J-327; J&J-202; IMERYS 219720; IMERYS 051370; IMERYS 238270; IMERYS 051442; IMERYS 051436; IMERYS 442232; JNJ 000063951; JNJMX68\_000004296; IMERYS 548407, attached hereto as **Exhibit 50**.

<sup>51</sup> See IMERYS 548366; IMERYS 189001; IMERYS 130504; IMERYS 130504; IMERYS 130504; IMERYS 130504; IMERYS S499486; IMERYS 499264; JNJ 000375383; IMERYS 533753; IMERYS 533694, attached hereto as **Exhibit 51**.

The presence of asbestos minerals in J&J's talcum powder is not limited to Italian and Vermont talc. Asbestos was also reported in Chinese talc in 2009<sup>52</sup> and in 2010, Ed McCarthy, the Technical Director for Imerys, reported tremolite in Chinese talc ores.<sup>53</sup> Testing indicated the presence of chrysotile particles in Chinese talc as recently as 2016.<sup>54</sup>

**b. J&J likewise identified fibrous talc during testing**

Fibrous talc has been reported on numerous occasions in both talc ore and J&J Talcum Powder Products. Fiber-like talc was found in analyses by commercial labs and others as early as the 1970s.<sup>55</sup> In a 1971 report to J&J, the Colorado School of Mines Research Institute identified both talc and non-talc needles in Italian talc product.<sup>56</sup> In a 1970 report, petrographic examination of thin sections from the Hammondsville mine (Vermont) showed that up to 20% of the talc ore was fibrous.<sup>57</sup> Between 1974 and 1977, McCrone evaluated various samples submitted by J&J's Windsor Minerals and found they contained fibrous talc.<sup>58</sup> A memorandum submitted from J&J's outside testing lab R. J. Lee Group indicated, as recently as

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<sup>52</sup> See IMERYYS 309326, attached hereto as **Exhibit 52**.

<sup>53</sup> See IMERYYS 081025, attached hereto as **Exhibit 53**.

<sup>54</sup> See JNJ 000521616, attached hereto as **Exhibit 54**.

<sup>55</sup> See IMERYYS 210707 at 802, attached hereto as **Exhibit 55**.

<sup>56</sup> See J&J 256, attached hereto as **Exhibit 56**.

<sup>57</sup> See JNJ 000245005 at 040, attached hereto as **Exhibit 57**.

<sup>58</sup> See IMERYYS 210707, attached hereto as **Exhibit 58**.

2009, that fibrous talc was present in talcum powder used to source J&J Talcum Powder Products.<sup>59</sup>

A summary of the charts of positive fibrous talc test results that appear in the reports of Drs. Cook and Krekeler reports is provided below.<sup>60</sup> The chart includes the results of positive tests arising from the 1940s, 1950s, 1970s, 1980s, and 1990s.

Decade	Number of Positive Tests	Source	Types of Asbestos Found
1940	1 <sup>61</sup>	Italy	fibrous talc
1950	1 <sup>62</sup>	Italy	fibrous talc 8-10%
1970s	33 <sup>63</sup>	Vermont	fibrous talc 10-20%

<sup>59</sup> See JNJ 000092227, attached hereto as **Exhibit 59**.

<sup>60</sup> Amended Cook Report at 21-28; Krekeler Report at 23-29.

<sup>61</sup> See JNJ 000085374, attached hereto as **Exhibit 60**; JNJNL61\_000000266, attached hereto as **Exhibit 61**.

<sup>62</sup> See JNJNL61\_000001341, attached hereto as **Exhibit 62**.

<sup>63</sup> See JNJS71R\_000001978; JNJ 000234805; JOJO-MA2330-0001; JNJNL61\_000024657; JNJNL61\_000024650; JNJNL61\_000032036; JNJNL61\_000023234; JNJ 000229914; JNJNL61\_000024449; JNJ 000238826; JNJ 000248023; JNJ 000314680; JNJNL61\_000025152; JNJS71R\_000009825; JNJS71R\_000007083; JNJS71R\_000000139; JNJ 000086280; JNJ 000232897; JNJS71R\_000002199; JNJ 000246844; JNJ 000346572; JNJ 000222851; JNJ000252742; JNJS71R\_000011316; JNJNL61\_000064162; JNJNL61\_000064161; JNJNL61\_000006591; JNJNL61\_000043243; JNJNL61\_000043244; JNJNL61\_000043245; JNJNL61\_000043246; JNJNL61\_000006591; JNJNL61\_000027053; JNJ 000065666; IMERYYS 210824; JNJ 000346747; IMERYYS 210700; IMERYYS 210701; JNJNL61\_000043271; JNJNL61\_000043272; JNJNL61\_000006591; JNJ 000314406; IMERYYS 210810; IMERYYS 210811; IMERYYS 210812; IMERYYS 210801; IMERYYS 210802; IMERYYS 210803; IMERYYS 210794, attached hereto as **Exhibit 63**.

		Italian	Talc needles 0.65-2.2% Talc fibers Fibrous talc particles Fibrous talc 1%
1980s	3 <sup>64</sup>	Vermont	fibrous particles
1990s	2 <sup>65</sup>	Vermont	Fibrous talc Fibrous structures indicative of talc
Undated	2 <sup>66</sup>	Italian Vermont	Fibrous talc Talc fibers

The positive test results for asbestos and fibrous talc are consistent with the published geological literature and make clear that the mines from which J&J's Talcum Powder Products were sourced as well as the finished products, contained asbestos and fibrous talc for decades.

**B. The results of the testing of historical J&J talcum powder samples by Drs. Longo and Rigler are consistent with the published literature and testing done by J&J and Imerys Talc America, Inc.**

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<sup>64</sup> See IMERYS 210788; IMERYS 210789; IMERYS 210790; IMERYS 210791; IMERYS 210792; IMERYS 210793; IMERYS 210794; IMERYS 210795; IMERYS 210796; IMERYS 210797; IMERYS 210798; IMERYS 210799; IMERYS 210758; IMERYS 210724, attached hereto as **Exhibit 64**.

<sup>65</sup> See JNJ 000281919; JNJ 000281921; IMERYS 477879, attached hereto as **Exhibit 65**.

<sup>66</sup> See JNJ 000260807; JNJ 000269904, attached hereto as **Exhibit 66**.

Dr. William Longo and Dr. Mark Rigler tested historical J&J Talcum Powder Product samples produced in this litigation.<sup>67</sup> All of the samples tested were finished product taken straight from J&J Baby Powder and Shower to Shower historical bottles. The Imerys rail car samples are samples of milled product (or processed product) taken just prior to the talcum powder being shipped for bottling.<sup>68</sup>

Drs. Longo and Rigler found that approximately 67% of the samples contained amphibole asbestos.<sup>69</sup> By sample type, 19 of 28 (68%) J&J's Baby Powder samples were positive for amphibole asbestos, 17 of 22 (77%) Shower to Shower samples were positive for amphibole asbestos, and 8 of 15 (53%) samples taken from Imerys' individual railcars were positive for amphibole asbestos.

Importantly, Dr. William Longo found fibrous talc in recent studies of historical samples. In their January 15, 2019 report, Drs. Longo and Rigler reported that 54 of the 55 samples tested using the ISO 2262-1 PLM method contained fibrous talc, or 98%. The Blount/PLM method showed that 20 of 71 samples contained fibrous talc, or 28%.

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<sup>67</sup> See January 16, 2019 First Supplemental Rule 26 Expert Report of Dr. William E. Longo and Dr. Mark W. Rigler ("Longo and Rigler First Supp. Report"), attached hereto as **Exhibit 67**.

<sup>68</sup> Pier Dep. at 108:3-13.

<sup>69</sup> See Longo and Rigler First Supp. Report.

The overarching focus of J&J's motion is that Drs. Longo and Rigler failed to use a reliable methodology and that the results from the tests they performed should therefore be excluded. As will be outlined in greater detail below, Drs. Longo and Rigler used generally accepted and reliable methods to test the historical talcum powder samples produced in this litigation. To be clear, these same methods were advocated and used by J&J experts repeatedly. Their findings and conclusions stand alone. The results of Drs. Longo and Rigler's testing should not be viewed in a vacuum, however. The results are consistent with what is known about the geology of the talc deposits used to source J&J's Talcum Powder Products. Moreover, the results are consistent with historical test results in J&J's possession which also reveal the presence of asbestos and fibrous talc. These facts further underscore and support the reliability of Drs. Longo and Rigler's testing.

**C. Drs. William Longo and Mark Rigler are eminently qualified, and their testimony and opinions have been accepted by numerous courts**

**1. Dr. William Longo**

Although J&J does not directly challenge Drs. Longo's and Rigler's qualifications as experts in their respective fields, their respective curriculum vitae clearly demonstrate that they are qualified to testify in this case.<sup>70</sup>

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<sup>70</sup> See Longo CV, attached hereto as **Exhibit 68**; see also Rigler CV, attached hereto as **Exhibit 69**.

Dr. Longo has a Bachelor of Science degree in Microbiology, a Master of Science degree in Engineering, and a Doctorate of Philosophy in Materials Science from the University of Florida.<sup>71</sup> Since 1987, Dr. Longo has been employed as President of MAS, LLC.<sup>72</sup> For the last thirty years, Dr. Longo has studied the content, type, and release of asbestos fibers from asbestos-containing products.<sup>73</sup> As a materials scientist, Dr. Longo studies the relationships among structure, properties, synthesis, and performance of a wide range of materials.<sup>74</sup> In his work, Dr. Longo examines why and how materials behave under various conditions, such as temperature, pressure, stress or exposure to climatic conditions, and how materials are used in every aspect of people's lives.<sup>75</sup> Dr. Longo is a member of numerous organizations and professional groups specializing in the testing and analysis of asbestos-containing materials, including the Environmental Protection Agency (EPA) Peer Review Group for the Asbestos Engineering Program, the American Industrial Hygiene Association (AIHA), Materials Research Society, American Society for the Testing of Materials (ASTM), and the American Society of

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<sup>71</sup> *Id.*; *see also* February 5, 2019 Deposition of William E. Longo, Ph.D. ("Longo MDL Depo.") at 347:23-351:10, attached hereto as **Exhibit 70**.

<sup>72</sup> Longo CV.

<sup>73</sup> *Id.* at ¶ 3.

<sup>74</sup> *Id.* at ¶ 4.

<sup>75</sup> *Id.*

Materials.<sup>76</sup> Dr. Longo has given numerous lectures on the proper protocol to be used when analyzing the behavior of asbestos products, including “Settled Dust: Asbestos and Other Particulates,” “The Role of the Laboratory Manager, Quality Assurance Officer and the Analyst for NIST Accreditation,” and “Fundamentals of Asbestos Analysis by TEM.”<sup>77</sup>

At MAS, Dr. Longo analyzes and studies a wide spectrum of products and associated chemicals, including the levels of asbestos fibers released under certain circumstances.<sup>78</sup> Dr. Longo performs these tests under rigorously controlled laboratory conditions following the governmental standards promulgated by NIOSH and the EPA.<sup>79</sup> As a member of ASTM, Dr. Longo was responsible for writing the ASTM asbestos dust analysis standards.<sup>80</sup>

In addition, Dr. Longo has published numerous articles on the subject of the analysis and testing of asbestos-containing materials, including the quantification of asbestos particles released upon manipulation of these asbestos products in the manner performed in the work environment.<sup>81</sup> His articles include Demonstration of

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<sup>76</sup> *Id.* at ¶ 7.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at ¶ 6.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at ¶ 8.

the Capability of Asbestos Analysis by Transmission Electron Microscopy in the 1960's in *Microscope*; Asbestos Exposure During and Following Cable Installation in the Vicinity of Fireproofing in *Environmental Choices Technical Supplement*; Fiber Release During the Removal of Asbestos-Containing Gaskets: A Work Practice Simulation, published in the *Applied Occupational and Environmental Hygiene Journal* in 2002; and Zonolite Attic Insulation Exposure Studies, in the *International Journal of Occupational Environmental Health* (2010).<sup>82</sup>

Finally, Dr. Longo consults with plaintiffs' firms, defense firms, and outside of litigation with well-known companies such as Hitachi, Intel, BMW, Honda, Dow, and others.<sup>83</sup> Dr. Longo regularly performs work for clients not involved in litigation and utilizes the same generally accepted methodologies and analysis for testing outside of litigation as he does in the courtroom.<sup>84</sup> Dr. Longo has, unsurprisingly, been the subject of *Daubert* challenges—as have most experts in litigation. Dr. Longo's testimony has been overwhelmingly admitted in the face of such challenges, contrary to J&J's representations, *in this decade and those prior*.<sup>85</sup> More importantly and directly relevant to this case, Dr. Longo's testimony with respect to MAS's

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at ¶ 9.

<sup>84</sup> *Id.* at ¶ 10.

<sup>85</sup> See **Exhibit 71**, Longo and MAS admissions spreadsheet, attached hereto; see also Longo MDL Depo at 351:11-21.

testing of J&J talcum powder and corresponding findings has been admitted in the vast majority of courts in which he has been proffered as an expert.<sup>86</sup>

Dr. Longo's prior testimony regarding MAS's testing of J&J Talcum Powder Products in trials across the country clearly demonstrates his qualifications and the foundation for the testing methodology.

- The *Herford* case in Los Angeles, California.<sup>87</sup> The court determined that Dr. Longo's testimony was admissible circumstantial evidence of the plaintiff's asbestos exposures from the product; Dr. Longo's methodology was scientifically supported; and the disagreements among the expert witnesses should be decided by the jury.<sup>88</sup>

- The *Lanzo* case in New Jersey.<sup>89</sup> After a preliminary hearing, Judge Viscomi determined that Dr. Longo's testimony was admissible, and that the defendants' cross-examination point affected only the weight of the evidence.

“What the Court found compelling was the testimony of Dr. Longo insofar as he found that by doing the testing, the consistency of the product throughout and some of the tests that he conducted revealed the presence of asbestos. Some did not and so based upon his argument as to the consistency, which the Court found compelling, as to it being an indicia of reliability, the Court finds that it would be appropriate to deny

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<sup>86</sup> *Id.*

<sup>87</sup> See **Exhibit 72**, *Herford* case, attached hereto.

<sup>88</sup> *Id.*

<sup>89</sup> See **Exhibit 73**, *Lanzo* case, attached hereto.

the motion to exclude, allow the testimony, but certainly there are issues that would go to the weight of the evidence.”<sup>90</sup>

- The *Anderson* case in California.<sup>91</sup> Dr. Longo was admitted “to testify as to the methods he used in regard to analyzing samples and his analyzation [sic] as to other items as well. I think that’s a determination for the jurors to make in regard to whether or not they accept his opinion or not and what weight they give his opinion. So, the court would allow Dr. Longo’s methodology or his methods that he relied upon in regard to testing and any other test results that he may testify to....”<sup>92</sup>

- The *Boyd-Bostic* case in South Carolina.<sup>93</sup> The court determined that Dr. Longo has specialized knowledge that would assist the trier of fact, and is qualified by his knowledge, skill, experience, training, and education.<sup>94</sup> The court further determined that Dr. Longo’s testimony as to the presence or absence of asbestos in talcum powder products was admissible, especially talcum powder samples directly from J&J “because J&J would have had it for all that time period.”<sup>95</sup>

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<sup>90</sup> *Id.* at 10.

<sup>91</sup> See **Exhibit 74**, *Anderson* case, attached hereto at 1694:21-1695:3.

<sup>92</sup> *Id.*

<sup>93</sup> See **Exhibit 75**, *Boyd-Bostic* case, attached hereto at 98:1-100:8, 122:5-125:10.

<sup>94</sup> *Id.* at 98:1-18.

<sup>95</sup> *Id.* at 124:20-125:10.

- The *Ingham* case in St. Louis.<sup>96</sup> The court permitted Dr. Longo to testify, explaining his analysis, findings of bundles, findings of fibers, and number of fibers in bundles per gram of talcum powder.<sup>97</sup>
- The *Henry* case in New Jersey.<sup>98</sup> The court permitted Dr. Longo's testimony for the same reasons as in the *Lanzo* case.<sup>99</sup>
- The *Allen* case in Humboldt County, California.<sup>100</sup> The court again permitted Dr. Longo to testify regarding his generally recognized and accepted methodologies.<sup>101</sup>
- The *Leavitt* case in California.<sup>102</sup> The court admitted Dr. Longo as an expert on the topics of material science, testing for asbestos, bulk air and tissue, and assessment of exposure from an industrial hygiene approach."<sup>103</sup>

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<sup>96</sup> See **Exhibit 76**, *Ingham* case, attached hereto at 973:13-25, 979:15-982:9, 985:12-986:16.

<sup>97</sup> *Id.*; see also *Ingham* at 115:6-120:15, attached hereto as **Exhibit 77**.

<sup>98</sup> See **Exhibit 78**, *Henry* case, attached hereto at 82:25-86:22.

<sup>99</sup> *Id.*

<sup>100</sup> See **Exhibit 79**, *Allen* case, attached hereto at 3133:16-3136:10.

<sup>101</sup> *Id.*

<sup>102</sup> See **Exhibit 80**, *Leavitt* case, attached hereto at 27:8-21, 52:18-22.

<sup>103</sup> *Id.*

- The *Olson* case in New York.<sup>104</sup> The court permitted Dr. Longo to testify, concluding that J&J's arguments were "a matter for the jury. It goes to the weight of the evidence, and it's not something [for which] the [c]ourt can exclude a witness."<sup>105</sup>
- The *Rimondi* case in New Jersey.<sup>106</sup> The court determined that Dr. Longo "qualified as an expert in the fields of material scientist - - material science, testing of asbestos and assessment of asbestos exposures."<sup>107</sup>
- The *Schmitz* case in Alameda County California.<sup>108</sup> Dr. Longo was admitted to testify, with the court certifying Dr. Longo "as an expert in material science, forensic engineering, testing for asbestos, and exposure to asbestos."<sup>109</sup>
- The *Sizemore* case in South Carolina.<sup>110</sup> The court permitted Dr. Longo to testify regarding his testing, methodology, and findings, including the range of asbestos exposure experienced by talcum powder users.<sup>111</sup> The court concluded

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<sup>104</sup> See **Exhibit 81**, *Olson* case, attached hereto at 1456:2-1471:23.

<sup>105</sup> *Id.*

<sup>106</sup> See **Exhibit 82**, *Rimondi* case, attached hereto at 6:18-38:9.

<sup>107</sup> *Id.*

<sup>108</sup> See **Exhibit 83**, *Schmitz* case, attached hereto at 44:13-50:1.

<sup>109</sup> *Id.* at 62:13-77:10.

<sup>110</sup> See **Exhibit 84**, *Sizemore* case, attached hereto at 95:4-5, 96:16-97:3, 99:23-101:5, 102:14-25, 103:6-12.

<sup>111</sup> *Id.* at 105:14-20, 107:20-108:6.

“[a]nd all the other things you wish I would do about Dr. Longo - - ...[t]hat big, huge hunk of paper that would exclude him or limit his opinions, I’m not going to do that.”<sup>112</sup>

Numerous juries throughout the country have been allowed to consider the evidence that is at issue here, including three juries in New Jersey state court. The *Leavitt*, *Olson*, *Rimondi*, and *Sizemore* juries have considered, and the *Schmitz* jury is considering, MAS’s testing and results conducted pursuant to this Court’s comprehensive, stipulated order in these proceedings. Conversely, the only court that has excluded the specific evidence at issue in this motion—that is, MAS talcum powder testing—did so without allowing oral argument or conducting a Rule 104 hearing and not based on methodology, but concern about the chain of custody of the samples tested, a concern that is not present here.<sup>113</sup> The samples that MAS tested in the MDL were produced by J&J directly to the PSC in compliance with this Court’s order.<sup>114</sup>

## 2. Dr. Mark Rigler

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<sup>112</sup> *Id.* at 108:7-12.

<sup>113</sup> See Tersigni Cert., Exhibit E16, attached hereto as **Exhibit 85**.

<sup>114</sup> See Agreed Order and Stipulation Regarding the Johnson & Johnson Defendants’ Production of Talcum Powder Products & Talc Samples (Dkt. 4032); Agreed Order and Stipulation Regarding Production of Talc Samples from Imerys Talc America, Inc. (Dkt. 4757).

Dr. Rigler has a Bachelor of Science degree in biology from Villanova University, and also holds a Ph.D. in microbiology from the University of Georgia with a heavy emphasis on using electron microscopy techniques.<sup>115</sup> He has been trained in all phases of electron microscopy including morphological identification of tissues and materials, selected area electron diffraction (SAED), and energy dispersive x-ray analysis (EDS).<sup>116</sup> Dr. Rigler also understands the methods of tissue processing that are used by clinical pathologists, which include histological sample preparation for histological slide preparation and tissue analysis and identification at the optical microscopy level.<sup>117</sup> Dr. Rigler's training and experience has included all phases of tissue preparation and tissue sectioning for transmission electron microscopy, including tissue preparation for scanning electron microscopy and tissue preparation for cryo-electron microscopy.<sup>118</sup>

Dr. Rigler previously worked as a licensed clinical electron microscopy Laboratory Director for the State of Georgia.<sup>119</sup> He is now employed at MAS, LLC as the Chief Science Officer and Senior Consultant, where for the last 25 years he

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<sup>115</sup> See Rigler CV; *see also* February 6, 2019 Deposition of Dr. Mark Rigler ("Rigler MDL Dep.") at 219:21-220:8, attached hereto as **Exhibit 86**.

<sup>116</sup> Rigler CV at ¶ 2.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at ¶ 2.

has directed the analysis of a variety of materials and biological tissues by transmission and scanning electron microscopy.<sup>120</sup> This work has included the analysis of mineralogical particulates and microfibers including tremolite, actinolite, anthophyllite, chrysotile, amosite, and crocidolite asbestos.<sup>121</sup>

Dr. Rigler has designed custom analytical protocols for product and chemical studies and has extensive laboratory management experience.<sup>122</sup> Dr. Rigler helped develop the quality control program at MAS which requires certification by the National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (“NIST NVLAP”).<sup>123</sup> Dr. Rigler is responsible for ensuring that the studies conducted at MAS follow the quality protocols and standards required by various lab certification bodies.<sup>124</sup> Dr. Rigler has also testified in other litigation.<sup>125</sup> Although he has been the subject of *Daubert* challenges, Dr. Rigler’s testimony has never been excluded on *Daubert* grounds.<sup>126</sup>

### 3. MAS, LLC

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<sup>120</sup> *Id.* at ¶¶ 2-3; Rigler MDL Dep. at 220:20-223:2.

<sup>121</sup> Rigler CV at ¶ 2.

<sup>122</sup> Rigler MDL Dep. at 224:3-225-4.

<sup>123</sup> *Id.* at 224:3-225-4.

<sup>124</sup> *Id.* at 225:10-227:13.

<sup>125</sup> *See* Rigler Affidavit at ¶ 3, attached hereto as **Exhibit 87**.

<sup>126</sup> *Id.*

MAS, LLC is a leading engineering consulting firm, which provides a broad range of services including environmental and industrial hygiene and emissions testing.<sup>127</sup> To perform its work, MAS has employees with expert knowledge of a broad range of fields including materials sciences, chemistry, physics, biology, industrial hygiene, geology, mechanical engineering, and microscopy. The American Industrial Hygiene Association has accredited MAS for measurement of asbestos fibers by phase contrast microscopy and for the analysis of bulk samples of asbestos.<sup>128</sup> In addition, the National Volunteer Laboratory Accreditation Program has certified MAS for measurement of bulk samples and air samples of asbestos. MAS also performs consulting work for government agencies such as the Centers for Disease Control and the National Institutes of Health.<sup>129</sup> Further, MAS worked as an expert for the City of New York and the State of New York in their respective litigation against asbestos companies.<sup>130</sup> MAS has been involved in testing asbestos-containing materials for over thirty years, and has analyzed hundreds of thousands of asbestos samples.<sup>131</sup> MAS has been retained by both plaintiffs and defendants in

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<sup>127</sup> See Longo Certification at ¶ 9, attached hereto as **Exhibit 88**.

<sup>128</sup> *Id.* at ¶ 3.

<sup>129</sup> *Id.* at ¶ 9.

<sup>130</sup> *Id.*

<sup>131</sup> *Id.*

asbestos litigation.<sup>132</sup> MAS studies and videotape demonstrations are used for educational and training purposes in conjunction with the American Industrial Hygiene Association, American Society of Safety Engineers, the Environmental Institute, AHERA certification training and the U.S. Public Health Service.<sup>133</sup>

MAS utilizes multiple, standardized analytical techniques. The MAS methods include the very testing techniques routinely employed by and available to industry in the 1960s and 70s, as well as updated, standardized testing procedures.<sup>134</sup> For example, the aspect-ratio distribution for the asbestos fibers identified by Dr. Longo in his testing are virtually identical to a number of other analyses on undisputed asbestos samples, including those conducted by former consultant to J&J, Dr. Alice Blount, the National Institute of Standards Technology (NIST), and the United States Geological Survey (USGS).

Drs. Longo and Rigler are uniquely qualified to analyze the asbestos content of the J&J Talcum Powder Products. Because Drs. Longo and Rigler have special knowledge, skill, experience, training, and education on the topics to which they may testify, their testimony is admissible under the Federal Rules of Evidence.

### **III. ARGUMENT**

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<sup>132</sup> *Id.* at ¶ 11.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* ¶ 12.

**A. Drs. Longo and Rigler did not “re-define” asbestos and they utilized recognized methodologies in conducting their analyses**

Contrary to J&J’s arguments, Drs. Longo and Rigler did not “re-define” asbestos or asbestiform materials to reach a desired result. Only J&J has engaged in such tactics. Instead, Drs. Longo and Rigler employed standard and scientifically accepted definitions and methodologies in conducting their analyses.

**1. What is asbestos?**

Asbestos is defined, for health and regulatory purposes, by various agencies such as the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the United States Environmental Protection Agency (EPA). Two areas of critical inquiry in this case at this time are whether the talcum powder that Plaintiffs’ used (and were exposed to) contained asbestos, and whether such exposure provides a biologically plausible explanation for the cause of their ovarian cancer. This issue is one of health and safety, not an examination as to the commercial viability of asbestos.

There are several definitions of asbestos that differ based on the use and context. The United States Geological Survey has explained this issue well:

Asbestos has been defined by workers in many disciplines including those in the commercial asbestos industry and the mining industry, the public health community, those in the regulatory community, and the mineralogical and geological sciences. Many of these definitions are given in a compilation prepared by Lowers and Meeker (2002). It is clear from that compilation that *the definition of asbestos (and related*

*terminology) can vary depending on the source and purpose.* For example, a definition of asbestos appropriate for the asbestos cloth industry, which might require a very long, thin, highly flexible fiber might be different from that used in the asbestos cement pipe industry which could utilize a more brittle and perhaps shorter and wider fiber. Both of *these definitions could be vastly different from those used in the health community, where the concern is exposure, risk, and ultimately disease.*<sup>135</sup>

The definition applied by J&J's experts<sup>136</sup> is a commercial one used “for analysis of commercial-grade asbestos found in the workplace and in consumer products.... developed to specifically analyze for commercial-grade asbestos in media where there may be reason to expect its presence.”<sup>137</sup> Asbestos—as found in commercial asbestos products or an asbestos vein being analyzed for commercial viability—is entirely different from asbestos naturally occurring as an accessory mineral to talc. “In order to be of commercial value, asbestos must be in sufficient quality and purity for the application, and it must occur in sufficient abundance to be mined at a profit.”<sup>138</sup> This definition, while central in some contexts, is simply

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<sup>135</sup> See U.S. Geological Survey (“USGS”), Tabulation of Asbestos-Related Terminology (2002) at 37, attached hereto as **Exhibit 89** (emphasis added).

<sup>136</sup> This definition was offered by J&J's expert Dr. Sanchez, who has not been identified as an expert in the MDL, but J&J's position (here asserted by Drs. Dyar and Wylie) is the same.

<sup>137</sup> USGS at 37.

<sup>138</sup> *Id.*

beside the point in the context of this litigation, which involves significant risks of cancer faced by American women. As the USGS has noted:

*[The] criteria sometimes employed for identification and characterization of commercial-grade asbestos ... have not been shown to directly contribute to health effects and should not be the sole basis for exclusion of materials that may otherwise meet demonstrated health-related criteria* such as length, width, bulk chemistry, and perhaps surface chemistry.... [T]he counting criteria developed for analysis of asbestos in the workplace or in commercial products may not be appropriate for direct application to what is currently referred to as naturally occurring asbestos.<sup>139</sup>

No one would suggest that the asbestos found as an accessory mineral in talc is a commercially viable source for asbestos mining—it is referred to instead as a “naturally occurring” component of a deposit being exploited for other reasons. Commercial viability may rest on factors wholly unrelated to health and welfare, including the location, amount, and extractability of the deposit. This case is not seeking an answer to the question: *Are there commercially viable asbestos deposits within J&J’s source talc?* Instead, the relevant inquiry is *whether J&J’s products, specifically, its Talcum Powder Products, contained asbestos fibers that can cause disease.* The only appropriate counting criteria and analysis methods are those applied by the regulatory agencies that evaluate and regulate asbestos-related health hazards. And importantly, the standards of the regulatory agencies that evaluate and

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<sup>139</sup> *Id.* at 42 (emphasis added).

regulate asbestos-related health hazards<sup>140</sup>—relied upon by MAS and Drs. Longo and Rigler—are devoid of any mandate that an analyst somehow meet the general *definition* of asbestos by analytically determining tensile strength and/or flexibility.<sup>141</sup>

Why are the standards devoid of such a mandate? The answer becomes clear when one simply asks: “What is high tensile strength?”<sup>142</sup>

Q. Well, I’m asking. Well, just -- candidly, chrysotile has one of the highest tensile strengths out of any of the minerals that exist on earth; right?

A. It has a high -- but when you say a high tensile strength, what do you mean?

Q. Higher than other minerals.

A. It doesn’t say that in the protocol.

Q. I’m not saying higher than fishing line; right? We’re talking about minerals here.

A. You’re talking about minerals, but you’re putting a statement in that is suggestive that somehow you have to make a determination if it has, quote, a high tensile strength or high flexibility to be asbestos versus cleavage fragments or particles of some sort. It’s just a general definition. It’s not designed to actually measure any of this.

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<sup>140</sup> Pursuant to such standards amphibole fibers or bundles are “defined to have an aspect ratio equal or greater than 5-to-1 and a minimum length of 5.0” with substantially parallel sides. Longo MDL Dep. at 229:230:1; *see also* February 1, 2019 Longo and Rigler 2nd Supplemental MDL Report (“2nd Supplemental MDL Report”) at 12, attached hereto as **Exhibit 90**.

<sup>141</sup> *Id.*

<sup>142</sup> Longo MDL Dep. at 390:11-17; *see also id.* at 389:24-390:10.

And when you get to tremolite and anthophyllite, if you want to say chrysotile has the highest tensile strength, they have the lowest.<sup>143</sup>

The most that J&J's own expert, Dr. Dyar, could say on the matter was "the definition of a fiber includes the qualifier that it has to be flexible and have a high tensile strength"—she was unable to express any "analytical techniques used to measure tensile strength or flexibility," much less define or outline parameters for determining what flexible is or when and whether tensile strength was high in accord with the definition.<sup>144</sup>

Once a fiber is identified in accordance with the standard's counting criteria<sup>145</sup>, the method employed by MAS and Drs. Longo and Rigler mandates the additional steps to permit identification of the fiber as regulated asbestos or otherwise.<sup>146</sup> As Dr. Longo explained "[t]he whole protocol determines what is a

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<sup>143</sup> Longo Leavitt trial testimony at 390:22-392:21.

<sup>144</sup> See Deposition of Melinda Darby Dyar, Ph.D. ("Dyar Dep.") at 335:5-340:11, dated April 2, 2019 attached hereto as **Exhibit 91**.

<sup>145</sup> Standard counting criteria relied upon by MAS and Drs. Longo and Rigler includes AHERA and ASTM. Admittedly, AHERA is used "to clear schools after abatement." Longo Leavitt Dep. at 389:8-23. The ASTM method—with the same standard counting rules as AHERA—relied upon by MAS and Drs. Longo and Rigler, however, "has nothing to do with clearing schools, [y]ou could use it to see if there was contamination." *Id.*

<sup>146</sup> Longo MDL Dep. at 229:230:1; see also 2nd Supplemental MDL Report at 12.

regulated asbestos, and then the asbestiform and high tensile strength is just a general definition.”<sup>147</sup>

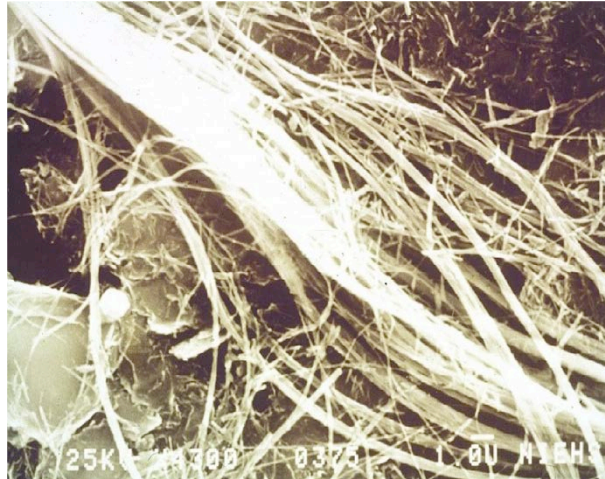
**2. Contrary to J&J’s arguments, regulators and scientists involved in public health issues do not distinguish between asbestos fibers and cleavage fragments**

The Court may wonder why there is a definitional divide between the parties. To be clear, it is J&J that is attempting to apply its own definition of “asbestos” in an effort to deflect scrutiny of the health hazards of its product—a tactic that is consistent with the strategy J&J has employed to evade and deflect throughout the last forty years. By simply redefining the term “asbestos,” J&J is arguing that fibers meeting the regulatory definition for asbestos are in fact non-asbestos “cleavage fragments.” This is important, of course, as fibers meeting the regulatory definition for asbestos have been found in both J&J’s talc ore and end-products.

Asbestos fibers are not uniform. They come in an infinite variety of shapes and sizes. Below is a picture of chrysotile asbestos. In this picture alone, there are thousands of fibers of all different morphologies (shapes): long, short, fat, thin, straight, curved, bundled, alone, etc.

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<sup>147</sup> Longo & Rigler MDL Dep. at 230:8-17.



Acknowledging asbestos fibers are not uniform, but come in an infinite variety of shapes and sizes, and that the accepted science is that all types of fibers can cause disease, the agencies that regulate asbestos have rejected the false distinction between “asbestos” and “cleavage fragments” that J&J is once again trying to foist on this Court. Responding to a report by the R.J. Lee Group—an expert J&J has previously utilized in talcum powder litigation, though not in this MDL—the EPA stated:

The R. J. Lee Report Applies a Geologic Definition rather than a Public Health Definition to Characterize Microscopic Structures - The R. J. Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. ***For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.*** The EPA Region 9 approach, which is supported by most public health agencies and scientists, as well as the American Thoracic Society, is based on the following: (1) The epidemiologic and health studies underlying EPA and Cal/EPA cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, and were unable to distinguish

between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that “it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,” (3) No well-designed animal or epidemiological studies have adequately tested the hypothesis that cleavage fragments with the same dimensions as a fiber are benign or that the human body makes any distinction, (4) Studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts, (5) There are no routine asbestos air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and ISO which differentiate between cleavage fragments and crystalline fibers on an individual fiber basis.<sup>148</sup>

The EPA concluded that “[i]n terms of epidemiological data and health outcomes, the *cleavage fragment argument is without merit*. For purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size and shape.”<sup>149</sup> **All regulated fibers are significant from a public health perspective.**

Public health and governmental agencies maintain the same or similar definitions for what constitutes a countable asbestos fiber when evaluating asbestos exposure because *the distinction Drs. Dyar and Wylie draw has no demonstrated impact on the ability to cause disease*. The argument J&J is making before this Court is in a word, reckless. As the EPA has stated, it also falls outside the bound of accepted science in the regulatory community. This Court should likewise reject it.

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<sup>148</sup> EPA Response to R.J. Lee at 2-3, attached hereto as **Exhibit 92**.

<sup>149</sup> *Id.* at 11-12 (emphasis added).

**3. Regulators and J&J (outside of litigation) employ similar methodology to identify asbestos**

Putting aside J&J's facile distinction between "asbestos" and "cleavage fragments" addressed above, there is near unanimity among regulators—and J&J—concerning the appropriate identification of asbestos fibers. After confirming through analysis of crystal structure and elemental chemistry that the particle is from the asbestos mineral family, the counting criteria determine what "counts" as an asbestos fiber. For reference, these include:

**OSHA:** A countable fiber under light microscopy is equal to or longer than 5 $\mu$  (microns) and has an aspect ratio (length-to-width ratio) of equal to or greater than 3:1.

**MSHA:** Same as OSHA.<sup>150</sup>

**EPA/AHERA:** A structure greater than or equal to .5 $\mu$  (microns) in length with an aspect ratio (length -to-width ratio) of 5:1 or greater and having substantially parallel sides.

**Johnson & Johnson:** "Asbestos is defined to be...chrysotile, and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite,

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<sup>150</sup> In 2005, RJ Lee Group (a third-party lab used by both J&J and Imerys) urged MSHA to change its counting rules to exclude cleavage fragments. MSHA declined. *See Exhibit 93* at 11286, attached hereto.

tremolite asbestos and actinolite.” J&J defines an “asbestiform mineral” as “An elongated particle with parallel sides and an aspect ratio  $\geq 3:1$ .”<sup>151</sup>

As described above, the agencies that regulate asbestos for health and safety purposes, as well as J&J, maintain very simple definitions that recognize the diverse morphology of asbestos fibers. As Dr. Longo explained in this case, a “[c]leavage fragment, typically for tremolite, is particulates that have an aspect ratio of somewhere between 1-to-1 to 1-to-2, but they will have the same chemistry and the same crystalline pattern.”<sup>152</sup> “[I]f it does have parallel sides, if it **does meet all the definitions** of the counting rules, you can call it what you like, but it’s regulated asbestos per the standard counting rules for every one of these TEM methods that I have referenced in my report.”<sup>153</sup>

#### **4. J&J seeks to create a false distinction when discussing asbestiform and non-asbestiform materials**

“Asbestiform” is a commercial geological distinction designed to designate certain asbestos deposits as commercially desirable or not. It has zero relevance to the health hazard of the material. Nonetheless, Dr. Longo has multiple reasons to

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<sup>151</sup> See June 28, 1977 J&J Memo “Audit Testing of Windsor 66 Talc for Asbestos,” attached hereto as **Exhibit 94**; “Analysis of Powdered Talc For Asbestiform Minerals by Transmission Electron Microscopy,” at 5, attached hereto as **Exhibit 95**; and March 21, 1995 “Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy,” at 8, attached hereto as **Exhibit 96**.

<sup>152</sup> Longo MDL Dep. at 238:13-19.

<sup>153</sup> Longo MDL Dep. at 239:2-22 (emphasis added).

conclude that what he found in the samples of J&J Baby Powder and Shower to Shower is, in fact, amphibole asbestos and not non-asbestiform chunks. Dr. Longo (1) found bundles of fibers, (2) found fibers longer than 20 microns, and (3) the average aspect ratio of the bundles and fibers he found ranged from 7:1 to over 20:1. These findings support the conclusion, based on generally recognized standards and peer-reviewed literature, that the J&J samples contain asbestos fibers.

In the samples of J&J Baby Powder and Shower to Shower that Dr. Longo tested, he found multiple examples of bundles of fibers, which Professor Blount in her 1991 peer-reviewed paper instructed are always indicative of asbestiform amphiboles.<sup>154</sup> Indeed, ISO 22262-1, the generally recognized standard for finding asbestos in bulk materials, states:

c) . . . observation of any of the following characteristics for the fiber type under consideration provides additional confirmation that the fibres are asbestiform:

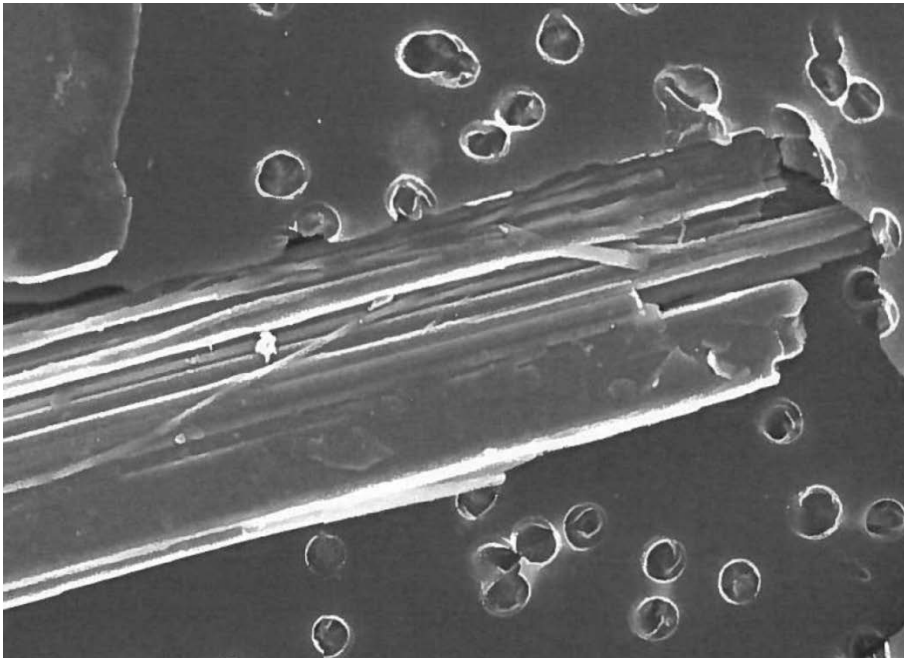
- 1) parallel fibres occurring in bundles,
- 2) fibre bundles displaying splayed ends,
- 3) fibres in the form of thin needles,
- 4) matted masses of individual fibres,

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<sup>154</sup> See Blount AM. 1991. Amphibole Content of Cosmetic and Pharmaceutical Talcs. *Environmental Health Perspectives*. 94:225-230, at 230 (“with true asbestiform amphiboles one generally sees some particles showing bundles of fibrils which removes any doubt about the nature of the amphibole.”) (emphasis added).

5) fibres showing curvature<sup>155</sup>

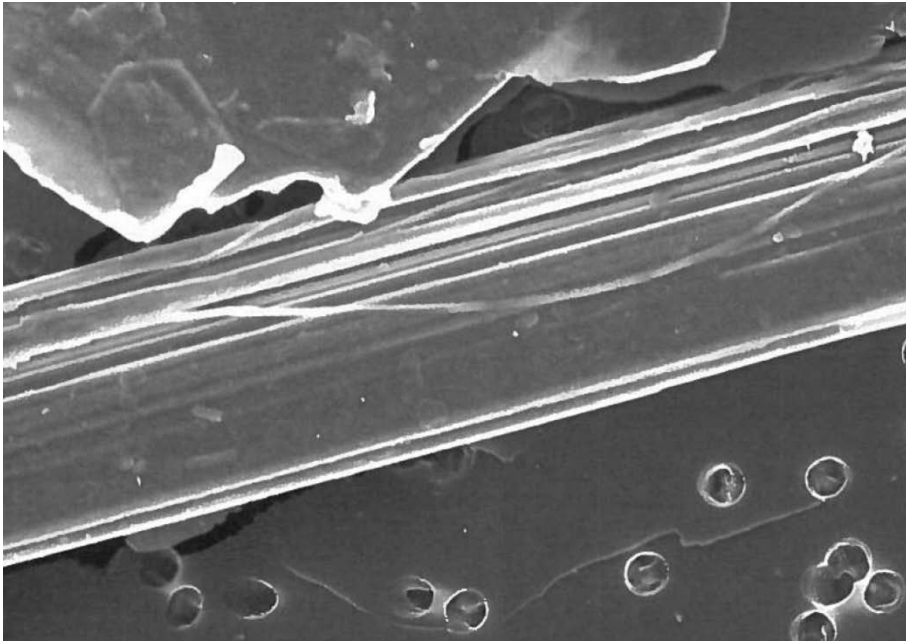
As the Court can see from a cursory inspection of Dr. Longo's scanning electron microscope photomicrographs of a 1978 Museum Sample of Johnson's Baby Powder, there are clearly bundles of fibers meeting these characteristics:<sup>156</sup>



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<sup>155</sup> See **Exhibit 97**, ISO 22262-1, Sampling and Qualitative Determination of Asbestos in Commercial Bulk Materials (2012), at 22-23.

<sup>156</sup> See Longo and Rigler MDL 1st Supplemental Report at p. 723.



(Top: Far terminal end of fiber bundle shown; Bottom: continuation of fiber bundle showing numerous thin fibrils showing flexibility).<sup>157</sup>

The average aspect ratios (ratio of length to width) of the fibers and bundles Dr. Longo found in his testing of J&J Baby Powder and Shower to Shower were consistent with the presence of asbestiform materials, not non-asbestiform materials. Dr. Longo found that the average aspect ratio of the asbestos fibers and bundles in the samples of J&J Baby Powder and Shower to Shower ranged from a low of 6.8 to a high of over 20, with many individual fibers or bundles having aspect ratios well into the 30s.<sup>158</sup> Notably, ISO 22262-1 states that the presence of any single bundle

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<sup>157</sup> See SEM Photomicrographs of 1978 JJ Museum Sample along with presentation by RJ Lee regarding asbestiform v. non-asbestiform for comparison, attached hereto as **Exhibit 98**.

<sup>158</sup> See Longo and Rigler MDL Report at 34-48.

or fiber longer than 20 microns in a sample, or a sample with fibers/bundles with an average aspect ratio higher than 5:1 supports the conclusion that the sample reviewed is asbestiform:

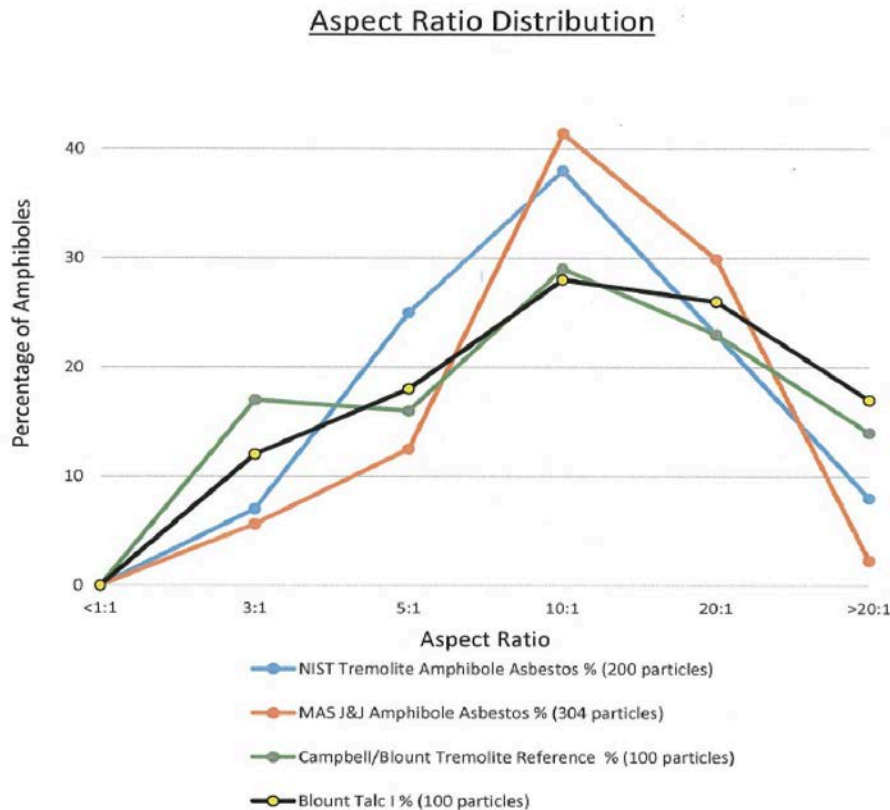
In general, for this part of ISO 22262, the presence of either the asbestiform or the non-asbestiform analogues of tremolite, actinolite, anthophyllite or richterite/winchite can usually be specified. If the majority of the amphibole fibres longer than 5 µm have aspect ratios equal to or lower than 5:1, and if the fibres do not exhibit any of the characteristics in c), it can be concluded that the amphibole is probably non-asbestiform, with the degree of certainty increasing with decreasing maximum aspect ratio. If any amphibole fibres longer than 5 µm with aspect ratios in the range of 20:1 or higher are observed, then it can be concluded that amphibole asbestos is probably present, with the degree of certainty increasing with increasing aspect ratio.<sup>159</sup>

Even J&J defines asbestos “to be . . . chrysotile, and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite asbestos and actinolite” and defines an “asbestiform mineral” as an “elongated particle with parallel sides and **an aspect ratio  $\geq 3:1$** .”<sup>160</sup> The aspect ratios found by Dr. Longo are consistent with both those found by Professor Blount, where the aspect ratio for “Tremolite asbestos” was 7:1, and with the 1977 Campbell Study:

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<sup>159</sup> ISO 22262-1 at 23 (emphasis added).

<sup>160</sup> See June 28, 1977 J&J Memorandum; see also March 21, 1995 J&J Test Method 7024 (emphasis added).



**B. Drs. Longo's and Rigler's microscopy follows accepted, reproducible methodologies**

**1. Drs. Longo and Rigler employed scientifically accepted testing methods**

MAS and Drs. Longo and Rigler have performed testing on talcum powder product samples that J&J and Imerys produced pursuant to this Court's comprehensive, stipulated order.<sup>161</sup> The talcum powder product samples ("historical samples") were from the 1960s, 1970s, 1980s, 1990s, and 2000s.<sup>162</sup> The historical

<sup>161</sup> Longo MDL Dep. at 351:22-352:13.

<sup>162</sup> *Id.* at 353:23-354:2.

samples’ source mines were Italy for the 1960s until the 1970s, Vermont for 1967 until 2003, and China for 2003 until the present time.<sup>163</sup>

To analyze the historical talcum powder samples, MAS and Drs. Longo and Rigler utilize basic instruments—“tools”—as well as sample preparations—“techniques.”<sup>164</sup> The tools utilized are the analytical transmission electron microscope (“TEM”), polarized light microscope (“PLM”), and X-Ray Diffraction (“XRD”). The techniques utilized are specified by International Standards Organization (ISO) methods 22262-1, 22262-2, 22262-3, and the peer-reviewed and published “Blount PLM method.”<sup>165</sup> For illustrative purposes, tool to technique pairs are:

<b><u>Tool</u></b>	<b><u>Technique</u></b>
TEM	ISO 22262-2 method <sup>166</sup> (heavy-density liquid separation)
PLM	Blount PLM method <sup>167</sup> (heavy-density liquid separation)
PLM	ISO 22262-2 method <sup>168</sup> (heavy-density liquid separation)

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<sup>163</sup> *Id.* at 354:3-8, 354:17-19.

<sup>164</sup> Longo at Leavitt Tr. at 65:9-66:2; Longo at Schmitz Tr. at 93:18-95:13.

<sup>165</sup> *Id.*; *see also* Longo and Rigler MDL Report at 4.

<sup>166</sup> Longo and Rigler MDL Report at 6, 8.

<sup>167</sup> *Id.* at 7-8.

<sup>168</sup> *Id.* at 6, 8.

PLM	ISO 22262-1 method <sup>169</sup> (no heavy-density liquid separation)
XRD	ISO 22262-3 method <sup>170</sup>

Concerning the techniques, one of the great challenges of analyzing a finely ground powder like talcum powder is removing enough of the platy talc so one can see the asbestos. Asbestos fibers are also difficult to detect in cosmetic talc because there are proportionally fewer of them in comparison to the amount of platy talc particles.<sup>171</sup> Because of this, the preparation methods for testing asbestos in talcum powder are critical to achieve a level of sensitivity that can detect asbestos fibers. To identify the amphibole asbestos fibers, MAS and Drs. Longo and Rigler based their testing on a scientifically sound and accepted method utilized by Alice Blount, Ph.D., in her 1991 peer-reviewed analysis—“Amphibole Content of Cosmetic and Pharmaceutical Talcs”—that found tremolite asbestos in “off-the-shelf” J&J Baby Powder.<sup>172</sup>

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<sup>169</sup> *Id.* at 5.

<sup>170</sup> *Id.* at 4-5.

<sup>171</sup> Longo MDL Dep. at 203:12-16.

<sup>172</sup> Longo MDL Dep. at 23:23-24:10, 25:21-26:2, 113:25-114:8, 197:22-23, 214:22-24; *see also* Blount 1991 article.

Blount's method utilizes the same tools (TEM, PLM, and XRD) as those used by J&J's experts but employs a preparation technique which results in a greater sensitivity specifically for the detection of amphiboles. In order to adequately examine talcum powder for the presence of amphibole asbestos, the talcum powder has to be "preconcentrated" through a heavy liquid separation method. Without using a preconcentration method, detecting asbestos in talcum powder is very unlikely (which makes the positive tests in J&J's files all the more damning, and any "negative" or "non-detect" finding expected). By purposefully avoiding the use of this preparation technique, J&J is able to continue to hide the true asbestos content of their talcum powder and report "non-detect" results from the use of inadequate methods.

Though this preparation technique (the "concentration method") was published by Dr. Blount in the 1990s, it has been known to J&J since the 1970s. In 1973, the Colorado School of Mines, consultants for J&J, reported that as the impurity level of talc becomes very low, to find the "proverbial 'needle in a haystack'" concentration is "considered *essential* to the success of any suggested procedure."<sup>173</sup> That same year, J&J wrote that their retained expert, Dr. Pooley, had developed techniques for pre-concentration of asbestos in talc, which he then used

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<sup>173</sup> See December 27, 1973 Colorado School of Mines "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers," attached hereto as **Exhibit 99**.

throughout the 1970s. Utilizing this preparation technique, Dr. Pooley detected levels of asbestos in J&J talc that he was unable to detect with other methods alone. When faced with Dr. Pooley's results, J&J rejected the method as "too sensitive."<sup>174</sup> In fact, it was because of its ability to find asbestos that J&J, when proposing testing methods to the CTFA, stated "[w]e *deliberately* have not included a concentration technique as we felt it would not be in worldwide company interests to do this."<sup>175</sup> As J&J explained in another internal memo, "[w]e really want to exclude concentration techniques in any proposed analytical procedure and are really looking at this method very quietly so that we will be informed and up-to-date with this area of technology. We want to avoid promotion of this approach."<sup>176</sup> Rather than heed the advice of their own consultants, J&J in conjunction with PCPC (formerly the Cosmetic, Toiletries and Fragrance Association (CTFA)) created their own talc-industry method to test for asbestos in talcum powder—CTFA's J4-1 method.<sup>177</sup>

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<sup>174</sup> See May 22, 1973 Internal J&J Memo "Proposed Specs for Analyzing Talc for Asbestos," attached hereto as **Exhibit 100**.

<sup>175</sup> See February 18, 1975 J&J Memo "We have deliberately not included a concentration technique..." attached hereto as **Exhibit 101**.

<sup>176</sup> See February 28, 1975 Internal J&J Memo "Review of CTFA Methodology for the Detection of Asbestos in Talc, as well as, Comments on TPF Methodology," attached hereto as **Exhibit 102**.

<sup>177</sup> See CTFA J4-1 method, attached hereto as **Exhibit 103**.

By 1974, J&J knew that they had to propose a testing method to the FDA “before the art advances to more sophisticated techniques with higher levels of sensitization.”<sup>178</sup> By 1976, J&J found it “disturbing” that the FDA was “getting into separation and isolation methodology which will mean concentration procedures.”<sup>179</sup> In order to avoid regulation by the FDA of cosmetic talc, and any requirement to use the concentration method, the Defendants created the J4-1 method in 1976. The J4-1 method was less stringent than FDA’s prior proposed method, which had a 0.1% detection limit. Instead the J4-1 method allowed a detection limit of merely 0.5%. This meant that cosmetic talc products may contain asbestos below the 0.5% detectable limit. By adopting the J4-1 method, J&J was able to: 1) continue to self-regulate cosmetic talc products; 2) avoid the FDA’s proposed lower detection limit for asbestos in cosmetic talc; 3) dissuade the FDA from further investigating concentration techniques, which would reveal asbestos in cosmetic talc; and most importantly, 4) claim that its talc was “free from” asbestos, knowing full well the detection level of the J4-1 could not find low level asbestos in the talcum powder, without the use of the concentration method.

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<sup>178</sup> See December 17, 1974 Memo to CTFA Estrin from J&J, attached hereto as **Exhibit 104**.

<sup>179</sup> See November 24, 1976 Internal J&J Memo Ashton to Lee, attached hereto as **Exhibit 105**.

**2. Drs. Longo and Rigler applied the scientifically sound (ISO) pre-concentration method, and repeatedly identified asbestos in the J&J Talcum Powder Products**

In 2014, the International Standards Organization (ISO) adopted the pre-concentration method in their ISO 22262-2 standard. MAS and Drs. Longo and Rigler applied this pre-concentration preparation method, included in the ISO method 22262-2, for finding and examining the levels of asbestos in J&J Talcum Powder Products (known as heavy-density liquid separation method).<sup>180</sup>

To perform these heavy-density liquid separation techniques, the talcum powder sample is placed in a tube with liquid, and then spun in a centrifuge, causing most of the asbestos fibers to fall to the bottom and most of the talc particles to float to the top.<sup>181</sup> The centrifuge tube is then flash frozen using liquid nitrogen, and a “guillotine-type apparatus” is used to cut the tip of the centrifuge tube off.<sup>182</sup> After the isolating samples to examine for potential amphibole asbestos fibers, MAS and Drs. Longo and Rigler view them by transmission electron microscopy, and count them according to federal and international health and safety standards.<sup>183</sup> An

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<sup>180</sup> *Id.*; *see also id.* at 161:17-24 (explaining a disadvantage of the method is that it cannot separate chrysotile asbestos from platy talc, because the particles have similar densities).

<sup>181</sup> Longo MDL Dep. at 203:12-16.

<sup>182</sup> Longo Schmitz Tr. at 101:19-102:22.

<sup>183</sup> Longo MDL Dep. at 196:17-24.

asbestos fiber is counted if it has an asbestos mineral type, has a crystalline structure, and has at least the minimum fiber shape and size, known as “aspect ratio,” i.e., greater than or equal to .5μ in length with an aspect ratio of 5:1 or greater, and substantially parallel sides.<sup>184</sup>

Utilizing this scientifically sound and generally accepted methodology<sup>185</sup>, MAS and Drs. Longo and Rigler repeatedly identified asbestos in the Johnson’s Baby Powder and Shower to Shower.<sup>186</sup> Specifically, MAS and Drs. Longo and Rigler analyzed:

- 34 historical samples of J&J Baby Powder, and found approximately 71% (24/34) with detectable levels of regulated asbestos;<sup>187</sup>
- 23 historical samples of J&J Shower to Shower, and found approximately 78% (18/23) with detectable levels of regulated asbestos;<sup>188</sup>
- 15 historical Imerys railroad car samples and found approximately 53% (8/15) with detectable levels of regulated asbestos.<sup>189</sup>

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<sup>184</sup> Longo MDL Dep. at 70:3-6, 71:4-11, 91:1-5, 91:8-13, 92:12-93:14.

<sup>185</sup> Longo MDL Dep. at 352:14-353:3.

<sup>186</sup> *Id.* at 354:9-355:10.

<sup>187</sup> *Id.* at 354:20-22.

<sup>188</sup> *Id.* at 354:23-25.

<sup>189</sup> *Id.* at 355:1-3.

Of the 72 total historical samples, approximately 66% (50/72) were found to contain detectable levels of regulated asbestos.<sup>190</sup> Of the 65 historical samples, eliminating the seven (7) Asian Johnson Baby Powder historical samples, 68% (44/65) were found to contain detectable levels of regulated asbestos.<sup>191</sup> As to fibrous talc, analysis using the ISO 22262-1 PLM method found 98% (55 of 56) contained fibrous talc.<sup>192</sup>

The heavy-liquid density separation method utilized by MAS and Drs. Longo and Rigler is reliable; so much so that R.J. Lee Group, which is regularly employed as J&J's expert in talcum powder cases, has utilized the very same method to identify asbestos in talc.<sup>193</sup> By the 1970s, J&J itself also knew about the method.<sup>194</sup> And as stated previously, it is now codified as an international standard testing method, ISO 22262-2.<sup>195</sup> The methods and results are also consistent with and supported by Dr. Blount's published and peer-reviewed method and findings. Not only does Dr.

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<sup>190</sup> *Id.* at 354:11-16.

<sup>191</sup> *Id.* at 355:3-7.

<sup>192</sup> *Id.* at 355:11-356:6; *see also id.* (Dr. Longo explaining the Blount PLM and TEM heavy density methods were also utilized for fibrous talc testing, but "the best predictor of fibrous talc would be the ISO PLM that does not use heavy density liquid....").

<sup>193</sup> Longo MDL Dep. at 23:23-24:10.

<sup>194</sup> *See Exhibit 106*, JNJ-1550 at 4; JNJ-058; JNJ-1228; JNJ-121.

<sup>195</sup> Exhibit ISO 22262-2 at 29; *see also* <https://www.sis.se/api/document/preview/917748/>.

Blount's article conclude that there is asbestos in J&J Baby Powder and the source mines for it, but she communicated her findings that *J&J's Vermont talc contains trace amounts of asbestos* in communications with Luzenac (now Imerys).<sup>196</sup>

**3. Drs. Longo and Rigler's "tools" and "techniques" are both sound and widely accepted**

As discussed previously, MAS and Drs. Longo and Rigler utilize several widely accepted tools and techniques. Through the employment of the different tools and techniques, and grounded upon their scientifically sound methodologies, MAS and Drs. Longo and Rigler have identified asbestos in J&J's Talcum Powder Products. Their conclusions that the asbestiform fibers identified were in fact asbestos, is founded on a generally accepted scientific protocol. Drs. Longo's and Rigler's testimony is reliably based on objective, verifiable testing results and the standard methods employed. MAS and Drs. Longo and Rigler's testing methodology is sound and admissible.

**4. Analytical Transmission Electron Microscopy and ISO 22262-2 method**

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<sup>196</sup> See Blount, 1991; Another geology expert on which Defendants regularly rely, Mickey Gunter, admits that not only does Blount's article demonstrate "asbestos in Johnson & Johnson talc products," but also that he has no criticism of Blount's density heavy liquid method that Longo followed. His criticisms are based not on Longo's method, but on his interpretation of the particles he identified, a dispute squarely within the purview of the trier of fact. See September 8, 2017 Deposition of Mickey E. Gunter, Ph.D. at 161:2-164:6, excerpts attached hereto as **Exhibit 107**.

ISO 22262 addresses the determination of asbestos in commercial bulk materials. ISO 22262-1 specifically notes “[s]imple analytical procedures such as polarized light microscopy are not capable of detecting or reliably identifying asbestos in some types of commercial products containing asbestos, either because the fibres are below the resolution of optical microscopy or because the matrix of material adheres too strongly to the fibres.”<sup>197</sup> As a consequence, where optical microscopy cannot provide reliable analyses of untreated samples (i.e. without density separation), ISO 22262-2 provides for extending the limits of detection using, inter alia, heavy-density liquid separation prior to microscopic examination or the use of TEM.<sup>198</sup> So, the ISO 22262-2 method is used for the quantitative determination of asbestos by gravimetric and microscopical methods.<sup>199</sup>

Pursuant to the ISO 22262-2 method, an asbestos fiber is counted if it has an asbestos mineral type, has a crystalline structure, and has at least the minimum fiber shape and size.<sup>200</sup> As a result, when MAS and Drs. Longo and Rigler employ TEM analysis using the ISO 22262-2 method on the historical talcum powder samples,

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<sup>197</sup> ISO 22262-1 at vii.

<sup>198</sup> *Id.*; see also ISO 22262-2 at Introduction and Scope.

<sup>199</sup> ISO 22262-2.

<sup>200</sup> Longo MDL Dep. at 70:3-6, 71:4-11, 91:1-5, 91:8-13, 92:12-93:14.

they utilize a three-step analysis that is grounded in the scientific method. Their methods are by no means novel or outside scientific norms:

look[ing] at three things: *The morphology. Is it fibrous? Does it meet the definition?* Very important, the microchemistry. Does it have a tremolite chemistry, the right ratios of magnesium, the calcium, and the one tall silicon peak? And does it have an amphibole-type d-spacing - - that's the - - that's the distance between the row of atoms - - that are consistent with tremolite?

So, it's not just one thing. Everything goes through a series of diagnostic tests. You know, A, yes. It has the right morphology. It's fibrous. Check.

*Second, the chemistry. Does the chemistry match?* And tremolite is very distinct. Check.

*[Third, d]oes it have an amphibole diffraction spacing between the atoms that are in the range of what you would expect for tremolite which are off standard x-ray cards for x-ray diffraction?* Check.

And there it is.

You can't - - you just can't rely on one thing. You put it all together and it says, yes, by all the standards, this is tremolite asbestos.<sup>201</sup>

A strength of utilizing TEM and the ISO 22262-2 method for the identification of asbestos is "that it's the most sensitive method out there in that it can detect single asbestos fibers."<sup>202</sup> A further strength is the inseparable three-steps that comprise the method; that is, the inseparable three-steps permit an analyst to:

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<sup>201</sup> Longo Schmitz Tr. at 175:9-176:10.

<sup>202</sup> Longo Schmitz Tr. at 88:15-21.

...fully characterize [the asbestos fibers] in that if you see a single small fiber, you can get the chemistry of it, utilizing EDXA, or energy dispersive x-ray. So, you can do microchemistry.

You can get crystalline structure information by doing the different diffraction patterns....And it allows you to take photographs of the micro - - these - - these microscopic fibers.

And so, if you have something there, you can fully characterize it. So, it still is the most sensitive method for this type of analysis.<sup>203</sup>

Of paramount import here, the mandated three-steps *of the methodology* used by MAS and Drs. Longo and Rigler are inseparable. Dr. Longo has explained, *ad nauseam*:

You [J&J attorney] keep saying alone, and you keep saying in a vacuum. That's not how it's done. The methodology doesn't say take the SAED alone. We have the chemistry that goes with it and the morphology. There's a reason it takes you through those steps.

....

...my answer is you do not look at these patterns alone. You're using peer-reviewed published protocol that walks you through morphology, EDXA, and a diffraction pattern. That's how the protocol goes.

It's not my protocol. These are the protocols for the ISO methods, for the AHERA methods, the ASTM - - TEM methods. There is a reason you do all of them.<sup>204</sup>

Nevertheless, now unable to mount any attack on the authenticity of the talcum powder samples MAS and Drs. Longo and Rigler tested, J&J endeavors to

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<sup>203</sup> Longo Schmitz Tr. at 88:15-89:8. As noted above in § II.C.1, *Schmitz* has relied upon, and presented to the jury, MAS's testing and results conducted pursuant to this Court's comprehensive, stipulated order in these proceedings.

<sup>204</sup> Longo MDL Dep. at 180:13-181:10.

deconstruct MAS's and Drs. Longo's and Rigler's scientifically sound methodology. *Daubert*, however, requires the proponent of the scientific evidence to show that the expert's conclusion has been arrived at "in a scientifically sound and methodologically reliable fashion," not that the expert's opinion or methodology is beyond reproach.<sup>205</sup>

On the whole, J&J's arguments boil down to credibility and conflicting expert opinion attacks that are more appropriately asserted in argument at trial and cross-examination. As *Daubert* specifically recognized, "cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" are the ordinary means to attack an opposing expert.<sup>206</sup> The United States Supreme Court has recognized that there is a range in which experts might reasonably differ on issues of science, and that such conflicting evidence should be admitted to aid the jury in deciding those issues.<sup>207</sup>

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<sup>205</sup> *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998); *In re TMI Litigation*, 193 F.3d at 665 (explaining that plaintiffs "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable" (citation omitted)).

<sup>206</sup> *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1999).

<sup>207</sup> *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 1953 (1999); *Ambrosini v. Labarraque*, 101 F.3d 129, 138-139 (D.C. Cir. 1996); *Globetti v. Sandoz Pharm. Corp.*, 111 F. Supp. 2d 1174, 1176 (N.D. Ala. 2000).

**a. Morphology: Drs. Longo and Rigler’s Visual TEM analysis is sound and widely accepted in the scientific community**

Contrary to J&J’s arguments, Drs. Longo and Rigler’s visual TEM analysis is the standard in the scientific community. The crux of J&J’s argument is that Drs. Longo and Rigler misidentified asbestos fibers or bundles when conducting their analysis. Essentially, this is an eye-of-the-beholder argument—Drs. Longo and Rigler employing industry-standard analysis see one thing, J&J seeking to avoid liability sees another. But this type of argument neither renders the underlying analysis unsound, nor does it undermine the fact that the approach and methodology are widely accepted. On these facts, a jury should be permitted to decide which party’s vision is more acute.

Pursuant to standard counting rules within the protocols relied upon by MAS and Drs. Longo and Rigler, amphibole fibers or bundles are “defined to have an aspect ratio equal or greater than 5-to-1 and a minimum length of 5.0” with substantially parallel sides.<sup>208</sup> Once a fiber is identified in accordance with the expressed criteria, the method mandates the additional steps to permit identification of the fiber as regulated asbestos or otherwise.<sup>209</sup>

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<sup>208</sup> Longo MDL Dep. at 229:230:1; *see also* Longo and Rigler MDL Report at 12.

<sup>209</sup> *Id.*

MAS and Drs. Longo and Rigler rely on the generally accepted scientific literature and regulations in testifying that bundles of fibers found via TEM are asbestos fibers. A fiber bundle is a “structure composed of parallel smaller diameter fibers attached to longer lengths.”<sup>210</sup> It is generally accepted that bundles of parallel amphibole fibers show that the fibers are asbestiform.<sup>211</sup> The mineral particles counted by Dr. Longo as asbestos meet the dimensional criteria of asbestos fibers. Dr. Longo also explained that “parallel fibers occurring in bundles” and “fiber bundles displaying splayed ends” and high aspect ratios are indicative of fibers being asbestiform and those opinions are well-accepted.<sup>212</sup> J&J has offered no evidence that these amphibole particles with these dimensions are likely non-asbestiform. In fact, J&J’s own expert, Dr. Mossman, explained in her deposition that mineral particles with high-aspect ratios are not cleavage fragments by definition because you do not find non-asbestiform particles with those dimensions.<sup>213</sup> Hence, it is perfectly reasonable for Dr. Longo to rely on counting rules to classify the fibers he found as asbestos.

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<sup>210</sup> Longo MDL Dep. at 229:3-230:1.

<sup>211</sup> Longo Leavitt Dep. at 159:2-161:11, 347:8-349:5, 392:2-394:19 (citing publications and regulations in support of this principle), 397:3-399:23.

<sup>212</sup> Longo Leavitt Dep. at 160:6-21.

<sup>213</sup> See November 15, 2018 Deposition of Brooke T. Mossman, M.S., Ph.D., Leavitt Trial, (“Mossman Dep.”), excerpts attached hereto as **Exhibit 108**.

As to bundles to fibers ratio, Dr. Longo explained “[a]ll these materials are milled, and you’re dealing with an asbestos type tremolite-anthophyllite that’s brittle,” so there is no expectation of an equal, even distribution between bundles and fibers.<sup>214</sup> Correspondingly, “[b]ecause you’re dealing with accessory minerals [i]t just depends on where it’s being dug out of the mine.”<sup>215</sup> The focus, as it should be, “is that every asbestos fiber or bundle we identify meets the counting criteria for a regulated asbestos fiber or bundle per the TEM methods, both ISO, ASTM. That’s the most important thing.”<sup>216</sup> What MAS and Drs. Longo and Rigler “strive for, is following the protocol, following the standard counting rules, and identification.”<sup>217</sup>

Finally, J&J attempts to recast an internal quality control study at MAS as fatal to the content that Drs. Longo and Rigler’s team can consistently identify asbestos. The MAS TEM Coefficient of Variation for Tremolite Anthophyllite in Talc: Quality Control Study, was designed so that all analysts looked at the same material or grid squares to assess the consistency with which the analysts “count[ed] the same number of asbestos structures, so that you can get a coefficient of variation for the error in the counting the number of structures from one opening to the next.

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<sup>214</sup> Longo MDL Dep. at 60:2-22.

<sup>215</sup> Longo MDL Dep. at 59:19-60:1.

<sup>216</sup> *Id.*

<sup>217</sup> *Id.*

That's what it was designed for.”<sup>218</sup> All of MAS's analysts “agreed that this was tremolite, it came from the standard, and that their error of coefficient or counting rate error for the number of structures was six percent which is pretty good.”<sup>219</sup> Again, the focus, as it should be, “is that every asbestos fiber or bundle we identify meets the counting criteria for a regulated asbestos fiber or bundle per the TEM methods, both ISO, ASTM. That's the most important thing.”<sup>220</sup>

**b. Diffraction Pattern (SAED): Scientific standards do not require two images taken from different zone-axis orientations**

Selected Area Electron Diffraction (“SAED”) is a pattern analysis in which analysts are identifying a particular, in this case an amphibole type, diffraction pattern.<sup>221</sup> The d-spacing is the layers of atoms on top of each other; d-space is between the planes.<sup>222</sup> The “d-spacings are all tied back to a standard that every lab should have for these particular type of regulated asbestos structures.”<sup>223</sup> MAS has analyzed 200 particles in a National Institute of Standards and Technology (“NIST”) standard to generate standards of SAED.<sup>224</sup> MAS and Drs. Longo and Rigler use the

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<sup>218</sup> See Tersigni Cert. Exhibit E29 at 169:9-171:15.

<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> Longo MDL Dep. at 91:1-5.

<sup>222</sup> *Id.* at 140:18-141:4.

<sup>223</sup> *Id.* at 155:5-15.

<sup>224</sup> Longo MDL Dep. at 118:5-23.

standard formula of “the camera constant divided by the measured distance” to determine the d-spacing.<sup>225</sup>

To calibrate the SAED apparatus, MAS analysts “get the working distance, and typically they’re using the gold standard<sup>226</sup> for the rings and the working distance so the [analyst] can do that calibration.”<sup>227</sup> In performing SAED, MAS and Drs. Longo and Rigler use one zone axis for tremolite because “fibrous talc does not have any calcium in it [, a]nd what you’re looking for in an EDS pattern is make sure there’s no aluminum.”<sup>228</sup> For anthophyllite and anthophyllite solid series solution, MAS and Drs. Longo and Rigler use two zone axes.<sup>229</sup> As to talcum powder, MAS and Drs. Longo and Rigler use the “[c]hemistry and one SAED pattern that has the hexagonal dot pattern.”<sup>230</sup> As to the d-spacing verification, it merely solidifies the determination of whether the SAED is identifying regulated

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<sup>225</sup> Longo MDL Dep. at 157:25-158:12.

<sup>226</sup> The “gold standard” is when analysts “take something that’s fibrous and you put a gold film on the top so that you get the outer rings of the gold, which is a standard measurement, and then the working distance so you can calibrate.” *Id.* at 141:14-142:2. The standard is literally made of gold, albeit “a very small piece of gold wire - - - that you sputter, so you’re not using a lot.” *Id.*

<sup>227</sup> *Id.* at 141:10-13.

<sup>228</sup> *Id.* at 133:10-15.

<sup>229</sup> *Id.* at 133:16-134:5.

<sup>230</sup> *Id.* at 134:6-9.

asbestos.<sup>231</sup> “It’s all important[, but i]f you do this long enough, you can look at it and say that’s an amphibole diffraction pattern.”<sup>232</sup> Had MAS and Drs. Longo and Rigler received a d-spacing that did not verify a SAED determination of regulated asbestos “then we’d have something else to talk about today.”<sup>233</sup> “Again, nothing here is done in a vacuum of just one and nothing else.”<sup>234</sup> As Dr. Longo testified in his deposition:

Q. Now, if somebody were to say, Dr. Longo, wait a second, you didn't measure the space and do what's called a zone-axis measurement of this, so how can you possibly know that's an amphibole pattern, because you didn't measure it? Is that a fair criticism, in your view?

A. Absolutely not.

Q. And why -- why do you say that?

A. You don't need a zone-axis diffraction pattern. If all you had was a diffraction pattern and no chemistry to go along with it, then, yes, you need to do at least one zone-axis diffraction, and you have -- and that's

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<sup>231</sup> *Id.* at 183:8-184:2.

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*

<sup>234</sup> *Id.* at 134:14-21; *see also Id.* at 136:11-24:

Q. So same question. In a vacuum, all you have is the SAED pattern for one axis for something you otherwise would call tremolite. Does that uniquely and only identify tremolite?

<objection>

A. If you were going to do that, and you were - - for whatever reason that here is an SAED pattern, there is nothing else, if it was a zone axis, then you’d have to get two zone axes, and now you’re dealing with like no chemistry, no idea where the tremolite fiber came - - if it is tremolite. So, I would not do it. I can’t talk about what other people would do.).

how microscopists would have done it in the '70s and early '80s before EDXA or the microchemistry got so good, for lack of a better word. So, you don't need that. It's not required in any of the standard protocols to do that.

Q. Did George Yamate, years ago, 30 years ago, suggest zone-axis measurements?

A. George Yamate said for EPA Level 3, and if it's going to be a -- if it's going to be a legal case, you need to do zone -- you need to do a couple zone-axis diffraction patterns to verify.<sup>235</sup>

In the early 1980s, Dr. George Yamate authored a TEM protocol “typically called the Level 1, Level 2, Level 3 protocol.”<sup>236</sup> “The methodology is based on a TEM analytical protocol that is divided into three levels of effort: Level I, for screening many samples; Level II, for regulatory action; and Level III, for confirmatory analysis of controversial samples.”<sup>237</sup> Level 3 protocol was, and is, designed to be performed so that if the final air clearance<sup>238</sup> for removal of asbestos products (asbestos abatement) is legally challenged, the final air clearance can be defended.<sup>239</sup>

Unsurprisingly, J&J’s expert upon whose opinions its entire argument rests, Dr. Dyar, was unable to articulate any reliance material, other than Dr. Yamate, with

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<sup>235</sup> Longo Schmitz Tr. at 176:11-177:8.

<sup>236</sup> Longo Schmitz Tr. At 86:3-9.

<sup>237</sup> See Yamate Paper at 3, attached hereto as **Exhibit 109**.

<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

respect to asbestos, that states a SAED two zone axes determination is required in order to make a determination that a material is asbestos.<sup>240</sup> Any criticism J&J may have based on Dr. Yamate's opinions is a matter for cross-examination and weight, not exclusion.

In addition, the entirety of J&J's argument that "there are thousands of minerals with one d-spacing at one orientation within 5% of 5.2Å," and "MAS analysts failed to consider whether the measurements more closely match those of other minerals" is solely based on the opinions of Dr. Dyar.<sup>241</sup> Yet, when asked how many of those thousands of crystal structures have been found in the Vermont and/or Italian talc mines used by J&J, Dr. Dyar "ha[d] no idea, because I know nothing about the mineralogy of talc mines in Vermont or anywhere else."<sup>242</sup> "Again, nothing here is done in a vacuum of just one and nothing else."<sup>243</sup>

**c. Microchemistry (EDXA): Drs. Longo and Rigler properly performed their EDXA analysis**

Energy Dispersive X-ray Spectroscopy ("EDXA") or energy dispersive spectroscopy ("EDS")<sup>244</sup> "[p]rovides the inorganic, and depending on your

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<sup>240</sup> Dyar Dep. at 201:24-202:10.

<sup>241</sup> Def. Mem. at 55.

<sup>242</sup> Dyar Dep. at 240:24-241:11.

<sup>243</sup> *Id.* at 134:14-21.

<sup>244</sup> Longo MDL Dep. at 25:2-5 (EDXA and EDS are the same technique).

detector, organic chemistry for any particular elongated particulate.”<sup>245</sup> MAS has analyzed 200 particles in a National Institute of Standards and Technology (“NIST”) standard to generate standards of EDXA.<sup>246</sup> The EDXA determines the chemistry, “and the chemistry is unique.”<sup>247</sup> MAS and Drs. Longo and Rigler “don’t make any conclusions by eyeballing it.”

The first thing we do is look at it [the particulate] and say this could match the counting rules for a regulated elongated particle. It’s at least greater than .5 micrometers in length. These are measurements. These are not eyeballing. It has parallel sides and has at least a 5-to-1 aspect ratio or greater.

Then the EDXA for me is taken to see if it is consistent with the ratios and patterns I would expect for some - - for the types of regulated asbestos fibers we’re looking at.

And we’re not saying, okay, we’re going to eliminate this type or that type. It’s whatever’s present.

Then the SAED - - so it has a typical amphibole diffraction pattern. If it’s anthophyllite, potentially, we’ll rotate the stage 10 to 20 degrees to eliminate the once-in-a-blue-moon reflection of fibrous talc that some people claim that’s close to anthophyllite.

And after all that, then we would - - I would say that is a regulated asbestos fiber type. It meets all the criteria.

You keep saying eyeballing. That’s not really much of a term - -  
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<sup>245</sup> *Id.* at 70:3-6.

<sup>246</sup> *Id.* at 118:5-23.

<sup>247</sup> *Id.* at 87:19-88:2.

What we're doing is we're looking at a set criteria. No decisions are made ahead of time.<sup>248</sup>

As Dr. Longo further explained, there are "no minerals out there that ha[ve] all the characteristics of a specific type of a regulated asbestos fiber, and that's why you go through the analytical process. You can get other fibrous materials, but they'll have aluminum or the magnesium-to-silicon ratios are off."<sup>249</sup> The inseparable three-steps cannot be done in a vacuum; one cannot say

[h]ere's just an EDS pattern, I'm not going to give you any other information, I'm not going to let you look at what kind of - - it's a fibrous structure or it's a particulate. Not going to let you look at the SAED patterns.

It's not following the procedure we've used here for all these samples. So I can't comment on something that I wouldn't do as an expert coming in here just looking at an EDS pattern with - - EDXA pattern without any other information.

...

No. I wouldn't just take an EDS pattern by itself and then run it to see what other possible minerals in the world have the same elements.

I would only be testifying here that this is tremolite - - regulated tremolite asbestos based on the entirety of the analysis that's done for each of these fibers or bundles.<sup>250</sup>

No accreditation program, laboratory or otherwise, "require[s] you to run weight percentages, oxides, or any of that. You have to demonstrate your ability to

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<sup>248</sup> *Id.* at 92:6-93:25.

<sup>249</sup> *Id.* at 73:6-25.

<sup>250</sup> *Id.* at 127:13-128:18.

identify regulated asbestos. We've never had it be suggested that we are misidentifying tremolite in any circumstance.”<sup>251</sup> Quite simply, none of the testing methodologies used by MAS and Drs. Longo and Rigler—ISO 22262-1, ISO 22262-2 or Dr. Yamate—require that quantitative data be generated in order to analyze the chemical structure of a particle.<sup>252</sup>

J&J's expert, Dr. Dyar is unable to cite any standard requiring the EDXA data formula printouts.<sup>253</sup> In fact, Dr. Dyar cannot even point to a standard that requires a printout of the quantitative data similar to figure 7 of her report for purposes of analyzing the chemical structure of a mineral to determine whether it's consistent with asbestos.<sup>254</sup> To be sure, Dr. Dyar agrees that it's not necessary to print out the chemical composition if you already know what it is.<sup>255</sup> This principal would seem to apply when you have fewer choices and when asbestos is known to occur in the type of samples being reviewed. Dr. Dyar notes that if you have “no idea and no independent constraints on what mineral it could be or what the composition could be”—it is your “obligation to produce as much quantitative information as

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<sup>251</sup> *Id.* at 88:12-23.

<sup>252</sup> Dyar Dep. at 126:1-131:10

<sup>253</sup> See Expert Report of Melinda Darby Dyar, Ph.D. (“Darby Report”) at 23, attached hereto as **Exhibit 110**; Dyar Dep. at 126:1-131:10.

<sup>254</sup> Dyar Dep. at 124:14-131:17; 137:2-139:9.

<sup>255</sup> *Id.* at 155:25-157:1.

possible.”<sup>256</sup> However, this obligation, and J&J’s attempts to impart it on MAS and Drs. Longo and Rigler, ignores the experience and knowledge of MAS and Drs. Longo and Rigler surrounding EDXA identification of asbestos materials. MAS and Drs. Longo and Rigler were not looking for asbestos in an “unconstrained” environment; they were looking for asbestos in the context of the testing of historical samples where the mine or source of origin was known.

When confronted with numerous examples of EDS/EDXA analysis without quantitative data, including her own material, Dr. Dyar agreed that quantitative data was not always necessary.<sup>257</sup> In fact, Dr. Dyar acknowledged that it would not be appropriate to bring out the chemical analyses where the possible mineral was known based on independent studies.<sup>258</sup> Yet, the results of the 1991 peer-reviewed and published independent study of Dr. Blount’s analysis of Vermont talc is remarkably similar to MAS and Drs. Longo and Rigler’s findings, but completely ignored by Dr. Dyar and J&J.

Finally, neither MAS nor Drs. Longo and Rigler have redacted EDXA information.<sup>259</sup> And, J&J’s claims of prior redactions and forceful admissions are

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<sup>256</sup> *Id.* at 156:21-157:1.

<sup>257</sup> *Id.* at 158:5-8.

<sup>258</sup> *Id.*

<sup>259</sup> Longo MDL Dep. at 88:3-11.

devoid of merit. Of primary import is the inarguable fact that the data purportedly nefariously removed in the referenced situation has absolutely nothing to do with EDXA information. The referenced situation involved excel spread sheets, automatic population, analytical sensitivity, and detection limits.<sup>260</sup> Also important, when given the opportunity to clarify, Dr. Longo testified the excel spreadsheets automatically populate the removed data, the data was removed because “it’s for different types of analyses,” and the removed data altered no part of the analysis, testing, or reported findings<sup>261</sup> This testimonial clarification was not only accepted by the jury, who rendered a verdict in favor of the ovarian cancer victims, but the district court in its later denial of J&J’s motion for a new trial which addressed this issue.

**d. Polarized Light Microscopy (PLM)**

Polarized light microscopy (“PLM”) is “a very involved analysis.”<sup>262</sup> Using PLM, the analyst can perform various analyses. For example, dispersion staining, which does not actually involve staining, is “just a matter of changing the characteristics of the optical microscope, cutting the light down and changing the F-stop.”<sup>263</sup> Under dispersion staining, the light is being refracted around the fiber or

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<sup>260</sup> Longo at Ingham Tr.

<sup>261</sup> *Id.* at 1219:20-23, 1221:19-1222:4, 1222:25-1223:4.

<sup>262</sup> Longo at Schmitz Tr. at 192:21.

<sup>263</sup> *Id.* at 188:13-189:16.

bundle, and because of the color of the light being refracted around the fiber or bundle under polarized light, the fiber or bundle gives off a certain color.<sup>264</sup> That color, along with its positioning to the light, for example parallel and coming in a single direction, is called a vibration, but is actually a wavelength of light.<sup>265</sup> After identifying the color (wavelength), the analyst will look up the color and be provided the corresponding refractive indices.<sup>266</sup> The analyst can also rotate the light, so that the light is going through at a different direction, which will provide a different color and different corresponding refractive indices.<sup>267</sup>

The analyst can also examine the extinction angle.<sup>268</sup> To ascertain the extinction angle, the analyst will “keep turning it to some point and the light refracted through the material will be the same as the light around the material on a particular angle, causing the light to disappear.”<sup>269</sup> When the light disappears, this is called the extinction angle.<sup>270</sup>

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<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> *Id.*

<sup>267</sup> *Id.* at 189:25-190:5.

<sup>268</sup> *Id.* at 190:13-23.

<sup>269</sup> *Id.*

<sup>270</sup> *Id.*

The analyst can also analyze the elongation. To perform elongation, the analyst uses a 530-nanometer filter that changes the vibration of the light.<sup>271</sup> Elongation informs the analyst “how fast the light goes through the crystal via the orientation ... and the particular colors will tell you what type of asbestos this is.”<sup>272</sup>

As with any analytical procedure, PLM has its strengths and limitations. “The strengths of the method are that it can positively identify the different regulated asbestos mineral types and provide a qualitative estimate of the weight percent of asbestos.”<sup>273</sup> As stated before, ISO 22262-1 notes the limitations of PLM in the detection of asbestos because of the limited resolution of the optical microscope and the masking effects of other materials.<sup>274</sup> Dr. Longo testified accordingly, stating the optical technique polarized light microscopy is a very good technique as long as the amount of asbestos in there is high enough for it to detect.<sup>275</sup> In some cases when testing the historical talcum powder samples the use of regular PLM will be non-detectable, in “[s]ome cases you do find it [regulated asbestos] by regular PLM.”<sup>276</sup> “Both techniques [TEM and PLM] have their strengths and weaknesses. This type

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<sup>271</sup> *Id.* at 192:10-20.

<sup>272</sup> *Id.*

<sup>273</sup> Longo and Rigler MDL Report at 5.

<sup>274</sup> ISO 22262-1 at vii.

<sup>275</sup> Longo at Schmitz Tr. at 93:22-25.

<sup>276</sup> *Id.* at 106:17-107:3.

of analysis [the analysis of talcum powder], in my opinion, needs the suite of techniques: the PLM, the Blount PLM, and TEM.”<sup>277</sup>

Recognizing the strengths and limitations, MAS and Drs. Longo and Rigler utilized PLM, along with the techniques of ISO 22262-1, and the peer-reviewed and published Blount PLM method.<sup>278</sup> J&J criticizes Drs. Longo and Rigler’s methodology in relation to 37 samples analyzed by Lee Poye of J3 Resources.<sup>279</sup> Of the 37 samples:

- 21 were tested using ISO PLM by MAS and Drs. Longo and Rigler;
- 37 were tested using ISO PLM by J3; and
- 37 were tested using Blount PLM by MAS and Drs. Longo and Rigler.<sup>280</sup>

As shown above, only 21 samples were tested using ISO PLM by MAS and Drs. Longo and Rigler. So, although 37 samples were tested using ISO PLM by J3, only 21 samples are available for comparison between the two laboratories. Of the 21 samples tested: 13 of the samples were no-detects by both MAS and J3, and only 8 of the samples detected regulated asbestos by MAS and Drs. Longo and Rigler and were no-detects by J3. Contrary to J&J’s assertions that these results establish a lack

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<sup>277</sup> Longo MDL Dep. at 163:22-164:16.

<sup>278</sup> Longo and Rigler MDL Report at 7-8.

<sup>279</sup> Def. Mem. at 76-78.

<sup>280</sup> *Id.* at 49-51.

of consistency and reliability and MAS and Drs. Longo and Rigler again “failed their own test,” the variation in these results is neither atypical of the scientific process nor illustrative of a failure to apply sound methodology. Although both MAS and J3 follow the ISO 22262-1 method, neither straying from nor using “any different methodology,” “the time [spent analyzing], high resolution, aberration-corrected lenses, [and] [real-time view] digital cameras” employed exclusively by MAS can and do occurrence unharmonious findings.<sup>281</sup> Dr. Longo has also testified generally, explaining that the variation in these, or any other similar results is neither atypical of the scientific process nor illustrative of a failure to apply sound methodology.

Q. Okay, if you took a split from a single bottle and you had two analysts look at it, would you expect them to identify the same kinds of asbestos, assuming there was asbestos spotted?

<objection>

A. Not necessarily, no.

Q. Okay. So one could say I see tremolite and another could say I see anthophyllite and you don’t think that it - - that demonstrates a problem?

<objection>

A. If the chemistry is right, the - - and they have identified it correctly, no. Many of these samples have two types of asbestos in it.<sup>282</sup>

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<sup>281</sup> Longo at Leavitt Tr. at 189:22-190:12, 194:20-195:11.

<sup>282</sup> Longo MDL Dep. at 51:17-52:6.

Q. If one of you scientists looked at a J&J bottle of talc and found a particular concentration of a particular kind of asbestos, would you - - do you believe to within a scientific - - a degree of scientific - - reasonable scientific degree of certainty that at second scientists following proper procedures would find the same?

<objection>

A. I think we already talked about this. I would never expect a second scientist or a second analyst going in with a separate prep sample finding the exact amount. And again, it depends on how many is there.

We did discuss this once. If it's one or two and the second analyst found none, that's in the margin of error, or it's looking for the needle in the haystack sort of analogy.

If one analyst found 50 and the other found zero, yes, that's a problem, like we already discussed. Again, I would have to look at the data to determine if it's a problem or not.<sup>283</sup>

With regard to J&J's contention that "there were only three instances where Drs. Longo and Rigler detected asbestos by Blount PLM where they did not by ISO PLM[,] [b]ut there were as many instances where they detected asbestos by ISO PLM where they did not by Blount,"<sup>284</sup> such contention is incorrect. Again, only 21 samples were tested using ISO PLM by MAS and Drs. Longo and Rigler. So, although 37 samples were tested using Blount PLM by MAS and Drs. Longo and Rigler, only 21 samples are available for comparison between the two techniques.

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<sup>283</sup> *Id.* at 55:11-56:8.

<sup>284</sup> Def. Mem. at 77; *see also id.* at chart at 77-78.

Of the 21 samples tested: 10 samples were no-detects under both ISO PLM and Blount PLM, 6 samples detected regulated asbestos under both ISO PLM and Blount PLM, 3 samples detected regulated asbestos under Blount PLM and were no-detects under ISO PLM, and 2 samples detected regulated asbestos under ISO PLM and were no-detects under Blount PLM. Accordingly, there were *not* as many instances where regulated asbestos was detected by ISO PLM and not detected by Blount PLM as there were instances where regulated asbestos was detected by Blount PLM and not detected by ISO PLM. Further, Blount PLM is not without its own strengths and limitations. One such limitation is that the density of low-iron anthophyllite is comparatively equivalent to the density of liquid used for separation; that is, the low-iron anthophyllite will float to the top after separation, not fall down to the bottom.<sup>285</sup> ISO PLM does not suffer from the same inability to detect low-iron anthophyllite. Lastly, using Blount PLM, approximately 57% (41/72 historical samples) were positive for detectable levels of regulated asbestos.<sup>286</sup> Comparatively, using ISO PLM approximately 32% (18/56 historical samples) were positive for detectable levels of asbestos.<sup>287</sup> In view of this, the overall PLM findings revealed a greater percentage of samples positive for detectable levels of regulated asbestos using

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<sup>285</sup> Longo MDL Dep. at 132:12-20, 318:14-319:7, 355:17-356:6.

<sup>286</sup> Longo and Rigler 2nd Supp. MDL Report at 8.

<sup>287</sup> *Id.* at 7.

Blount PLM, supporting the construction that using heavy liquid separation (concentration) would increase the analytical sensitivity of the PLM analysis.

Finally, as to J&J's claim that neither MAS nor Drs. Longo and Rigler can "reliability [sic] differentiate between bundles and fibers when using PLM[,]"<sup>288</sup> such claim is devoid of merit. To be clear, MAS and Drs. Longo and Rigler "[w]ere not using our methodologies [for PLM analyses,] [w]e're using the standard protocol methodologies."<sup>289</sup> Determinations of whether a fiber or bundle is regulated asbestos, and ultimate determinations as to whether the PLM was positive for asbestos are not mere opinions rendered by the analyst, but are determined in accordance with the applicable protocols. If "[i]t meets the definition[,]" it has the right crystalline information[,]" it meets all the difference definitions ... that is not an opinion."<sup>290</sup>

Indubitably, all of J&J's PLM exclusion claims disregard the Third Circuit's long-standing adage that "[a]s long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process-competing expert testimony and active cross-examination-rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or

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<sup>288</sup> See Def. Mem. at 78-80.

<sup>289</sup> Longo MDL Dep. at 216:14-20.

<sup>290</sup> *Id.* at 206:18-261:1.

satisfactorily weigh its inadequacies.” *U.S. v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004).

**C. IARC and medical and scientific literature provide reliable evidence that asbestos can cause ovarian cancer**

The issue presently before the Court is whether the PSC’s experts have presented reliable evidence that the use of J&J’s Talcum Powder Products can cause ovarian cancer. The opinions of the PSC’s experts are supported by the totality of extensive peer-reviewed literature on 1) migration of particulates within the female genital tract or through inhalation, 2) the known carcinogenic constituents in talcum powder (including *asbestos*, *fibrous talc*,<sup>291</sup> heavy metals, fragrances, and other chemicals), 3) the known inflammatory properties of talcum powder, and 4) the known role inflammation and oxidative stress play in the pathogenesis of ovarian cancer.<sup>292</sup> The overwhelming evidence of the presence of asbestos and fibrous talc

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<sup>291</sup> In relation to fibrous talc, The PSC incorporates by reference the *Plaintiffs’ Steering Committee’s Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson’s and Johnson & Johnson Consumer Inc.’s Motion to Exclude the PSC’s Experts’ Opinions Related to Heavy Metals and Fragrances in Johnson’s Baby Powder and Shower to Shower*.

<sup>292</sup> The PSC incorporates the *Plaintiffs’ Steering Committee’s Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson’s and Johnson & Johnson Consumer Inc.’s Motion to Exclude the PSC’s Experts’ Opinions Related to Biological Plausibility* and highlights the following important points relating to ovarian carcinogenesis resulting from asbestos and fibrous talc.

in J&J's Talcum Powder Products provides additional and powerful support of the fact that the genital use of talcum powder can cause epithelial ovarian cancer.

**1. IARC classifies asbestos and talc containing asbestiform fibers as Group 1 carcinogens for ovarian cancer**

Asbestos is universally recognized as a potent human carcinogen. IARC's Monograph 100C (2012)<sup>293</sup> titled "Asbestos (Chrysotile, Amosite, Crocidolite, Tremolite, Actinolite, and Anthophyllite)" clearly states: "The conclusions reached in this *Monograph* about asbestos and its carcinogenic risks apply to these six types of fibres [chrysotile, actinolite, amosite, anthophyllite, crocidolite, and tremolite], and that includes *talc containing asbestiform fibres* [fibrous talc]." IARC ultimately concludes that asbestos causes mesothelioma and cancer of the lung, larynx, and *ovary*.

In reaching its conclusions regarding carcinogenicity, IARC considers exposure data, studies of cancer in humans, studies of cancer in experimental animals, and mechanistic and other relevant data.<sup>294</sup> IARC acknowledged that the literature examining the association between asbestos exposure and cancer of the ovaries was relatively sparse, because the workforce occupationally exposed to

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<sup>293</sup> IARC 2012, at 232.

<sup>294</sup> IARC 2010, preamble.

asbestos has been predominantly male.<sup>295</sup> However, IARC still determined the evidence to be sufficient.

*First*, despite J&J’s misleading arguments to the contrary,<sup>296</sup> IARC did *not* restrict its findings to occupationally exposed women, instead considering environmental, household, and general population exposures as well. For the general population, IARC identified “[c]onsumer products (e.g. cosmetics, pharmaceuticals)” as “the primary sources of exposure to talc for the general population.” Further, “inhalation and dermal contact (i.e. *through perineal application of talcum powders*) were considered “the primary routes of exposure”.<sup>297</sup> Inhalation was considered the primary route of exposure to talc in occupational settings.<sup>298</sup> Asbestos and talc fibers can reach the target organ – the ovary – by either route.<sup>299</sup> This evidence is clearly relevant to the association between talcum powder products and ovarian cancer.<sup>300</sup>

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<sup>295</sup> *Id.* at 253.

<sup>296</sup> Def. Mem. 20-24; 83-87.

<sup>297</sup> *Id.* at 232.

<sup>298</sup> *Id.*

<sup>299</sup> *Id.* at 232.

<sup>300</sup> See April 4, 2019 Deposition of Gregory B. Diette, MD (Defs.’ Expert) at 397:15-399:19, attached hereto as **Exhibit 111** (confirming the epidemiologic evidence related to asbestos exposure and ovarian cancer served as part of the basis for IARC’s conclusion that asbestos can cause ovarian cancer).

IARC found that a “causal association between exposure to asbestos and cancer of the ovary was clearly established, based on five strongly positive studies in women with heavy occupational exposure to asbestos.”<sup>301</sup> However, they also found that additional support was provided from studies showing that women and girls with *environmental*, but not occupational exposure to asbestos, had positive, though non-significant, increases in both ovarian cancer incidence and mortality.<sup>302</sup> IARC’s comprehensive analysis, as outlined in the *Monograph*, makes it clear that it did not limit its findings about the carcinogenic effect of asbestos on the ovary to only those individuals with occupational exposure.

Moreover, and significantly, J&J cites no support for its assertion that occupational exposure would be greater than the exposure of a women who applies talcum powder to her genital area regularly (often daily or multiple times per week) for an extended period of time. The assertion is made, but without support. There is no evidence to allow comparison between the degree of exposure with regular perineal talcum powder usage versus that with occupational or household exposure. In the case of genital talcum powder application, direct migration to the tubes and ovaries presents an important route of exposure, in addition to inhalation (the primary route in an occupational or household setting).

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<sup>301</sup> *Id.* at 256.

<sup>302</sup> *Id.*

*Second*, J&J’s argument that plaintiffs’ experts primarily rely on studies that only involved crocidolite asbestos is misleading and wrong. In reaching their opinions on talcum powder exposure and ovarian cancer risk, the PSC’s experts relied on the expert scientific review conducted by IARC and the medical and scientific literature cited therein. As the *Monograph* outlines in detail, the Working Group reviewed, evaluated and relied on studies that included chrysotile and amosite asbestos, not just crocidolite asbestos.<sup>303</sup>

*Third*, J&J argues that the results of the studies considered by IARC may be “potentially inflated due to other diseases, such as peritoneal mesothelioma, being misclassified as ovarian cancer.”<sup>304</sup> The Working Group “carefully considered the possibility that peritoneal mesothelioma may have been misdiagnosed as ovarian cancer”, but rejected misdiagnosis as an explanation for the observed increased risk.<sup>305</sup> A meta-analysis performed by Reid in 2011 found an increased risk of ovarian cancer in women exposed to asbestos (*non-occupational* and occupational).<sup>306</sup> These authors suggested that misclassification between peritoneal

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<sup>303</sup> IARC, 2012 at 38.

<sup>304</sup> Def. Mem. at 22-23, 81.

<sup>305</sup> IARC, 2012 at 256.

<sup>306</sup> See Reid, A., N. de Klerk, and A. W. Musk. “Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis.” *Cancer Epidemiology Biomarkers & Prevention* 20, no. 7 (July 1, 2011): 1287–95, attached hereto as **Exhibit 112**.

mesothelioma and ovarian serous carcinoma could be contributing to the observed risk, concluding that the IARC determination was premature and not wholly supported by the evidence.<sup>307</sup> However, the authors stated that “[w]hen only those studies that confirmed their ovarian cancer pathology were included in a meta-analysis, the effect estimate declined, although remained statistically significant.”<sup>308</sup>

*Fourth*, the Working Group also considered scientific literature reporting the presence of asbestos in ovarian tissue, with both non-occupational and occupational exposure to asbestos. Heller and colleagues (1996) found significant asbestos fiber burdens in 9 of 13 women with household asbestos exposure and in 6 of 17 women who gave no exposure history.<sup>309</sup> This study demonstrated that asbestos can reach the ovary and that women with a positive exposure history had asbestos detected more frequently and in higher counts.<sup>310</sup> The authors also suggested a possible role for sexual contact as a transporting vector for asbestos fibers.<sup>311</sup>

In response to IARC’s causal association between exposure to asbestos and ovarian cancer, Camargo and colleagues performed a meta-analysis to quantitatively

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<sup>307</sup> *Id.* at 1294.

<sup>308</sup> *Id.* at 1292.

<sup>309</sup> Heller, D. S., et al. “Asbestos Exposure and Ovarian Fiber Burden.” *American Journal of Industrial Medicine* 29, no. 5 (May 1996): 435–39, attached hereto as **Exhibit 113**.

<sup>310</sup> *Id.* at 439

<sup>311</sup> *Id.* at 438

evaluate this association in occupational and non-occupational settings.<sup>312</sup> According to the authors of this study, the results supported the conclusion by IARC that exposure to asbestos is causally associated with an increased risk of ovarian cancer.<sup>313</sup>

*Fifth*, in addition to IARC's assessment and the epidemiological studies demonstrating a causal link between asbestos exposure and ovarian cancer, additional peer-reviewed medical literature accepts asbestos as a risk factor for epithelial ovarian cancer. The Institute of Medicine in their 2016 "state of the science" treatise on ovarian cancer identified asbestos as a "specific inflammatory factor" associated with ovarian cancer.<sup>314</sup>

**2. The presence of asbestos (and fibrous talc) provide strong support for the PSC's experts' opinions regarding biologic plausibility**

As has been argued extensively in relation to biologic plausibility, the PSC's experts have opined that talcum powder (and all of its constituents including asbestos) cause inflammation and inflammation and oxidative stress play a key role

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<sup>312</sup> See Camargo, et al., "Occupational Exposure to Asbestos and Ovarian Cancer: AMeta-Analysis." *Environmental Health Perspectives* 119, no. 9 (September 2011): 1211–17 ("Our study supports the IARC conclusion that exposure to asbestos is associated with increased risk of ovarian cancer."), attached as **Exhibit 114**.

<sup>313</sup> *Id.* at 1216.

<sup>314</sup> National Academy of Sciences, Engineering, and Medicine. 2016. *Ovarian cancers: Evolving paradigms in research and care*. Washington, DC: The National Academies Press.

in the pathogenesis of ovarian cancer. IARC's discussion of the biological plausibility of an association between asbestos exposure and ovarian cancer (contained in Section 4 of the Monograph) provides additional support of the PSC's experts' opinions. IARC found that there was a biologically plausible relationship between asbestos exposure and ovarian cancer in part because there are similarities between the pathogenesis of asbestos-related malignancies wherever they occur.<sup>315</sup> In support of its finding on biological plausibility, IARC relied in part on an experimental study that found that intraperitoneal injection of tremolite asbestos in guinea-pigs and rabbits produced epithelial changes in the ovaries "similar to those seen in patients with early ovarian cancer."<sup>316</sup>

The mechanism by which asbestos and talc fibers can cause cancer is well-described in the scientific literature. IARC proposed direct and indirect mechanisms, both associated with inflammation. In the direct mechanism, mineral fibers are shown to generate free radicals that directly induce genotoxicity as assessed by DNA breaks and oxidized bases in DNA. In the indirect mechanism, asbestos fibres induce macrophage activation and persistent inflammation that generate reactive oxygen and nitrogen species contributing to tissue injury, genotoxicity, and epigenetic alterations. Persistent inflammation and chronic oxidative stress have been

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<sup>315</sup> IARC, 2012 at 257.

<sup>316</sup> *Id.* at 281

associated with the activation of intracellular signaling pathways, resistance to apoptosis, and stimulation of cell proliferation.<sup>317</sup>

Defense Expert Brooke Mossman, in her 2018 review article on in vitro mechanisms for the carcinogenesis of “EMPs” (elongated mineral particles or fibers), confirms the mechanisms outlined by IARC in 2012, whereby long EMPs appeared to be promoters of cancers via a number of mechanisms such as inflammation, generation of oxidants, and instigation of cell division through epigenetic and signaling cascade processes.<sup>318</sup>

Prior to this MDL, J&J and its consultants *admitted* that the presence of asbestos in J&J’s Talcum Powder Products would present a biologically plausible explanation for the association between its products and ovarian cancer. Michael Huncharek, M.D. and Joshua Muscat, Ph.D., former J&J consultants and litigation experts, *published* their views that talcum powder contaminated with asbestos establishes biologic plausibility between the association of genital talcum powder

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<sup>317</sup> IARC, 2012 at 294.

<sup>318</sup> Mossman, Brooke T. 2018. “Mechanistic in Vitro Studies: What They Have Told Us about Carcinogenic Properties of Elongated Mineral Particles (EMPs).” Toxicology and Applied Pharmacology, July, attached as **Exhibit 115**.

use and ovarian cancer.<sup>319</sup> Notably, J&J has now abandoned them as litigation experts.

In a 2007 article, Muscat and Huncharek wrote: “If one is exposed to a mixture of talc and asbestos, it is reasonable to expect a carcinogenic effect as it contains a known carcinogen.”<sup>320</sup> And again, these J&J consultants wrote in 2011:

Clearly, [talcum powder] products could possibly represent a carcinogenic risk secondary to the asbestos contamination. It should be pointed out that this in no way implicates talc as a toxin as the problematic constituent of such products was the asbestos fibers, not talc.<sup>321</sup>

The evidence supporting the fact that J&J’s products contain asbestos (fibrous talc and other carcinogens) and that asbestos can cause epithelial cancer is robust, relevant and reliable. Plaintiffs’ causation experts properly rely on the overwhelming evidence that J&J Baby Powder and Shower to Shower contained asbestos (and other known carcinogens including fibrous talc). The presence of these carcinogens

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<sup>319</sup> See September 25, 2018 Deposition of Joshua E. Muscat, Ph.D. (“Muscat Dep.”) at 276:2-277:10, excerpts attached as **Exhibit 116**.

<sup>320</sup> Michael Huncharek, et al., Use of Cosmetic Talc on Contraceptive Diaphragms and Risk of Ovarian Cancer: a Meta-Analysis of Nine Observational Studies, 16 Eur. J. Cancer Prev. 422 (2007), attached as **Exhibit 117**.

<sup>321</sup> Michael Huncharek & Joshua Muscat, *Perineal Talc Use and Ovarian Cancer Risk: a Case Study of Scientific Standards in Environmental Epidemiology*, Eur. J. Cancer Prevention (2011), attached as **Exhibit 118**.

provides a credible biologic explanation for the association between talcum powder use and ovarian cancer.

**D. Reliable scientific evidence establishes that asbestos was present in the talc used to source J&J'S Talcum Powder Products**

Despite significant evidence to the contrary, J&J claims that the PSC lacks reliable scientific proof that asbestos was present in the talc ore used to source the products. J&J attempts to do this by going through test results and pointing out a few selected examples that were inadvertently included and not from the correct mines or talc that was used for industrial purposes. However, they were only able to do this for a handful of samples and Drs. Krekeler and Cook cite many more samples that J&J was not able to criticize. Even if the PSC concedes every specific instance J&J cites, there are over a hundred others that still stand as positive for asbestos or fibrous talc.

**1. The methodology and evidence relied upon by Drs. Cook and Krekeler is proper**

In addition to cherry-picking a handful of inconsistent test results and samples, J&J attempts to undermine the PSC's experts Drs. Cook's and Krekeler's methodology and document sources. However, both experts lay out their methodology and data throughout their reports and deposition testimony. In reaching his opinions, Dr. Krekeler evaluated the data including but not limited to x-ray diffraction data, core data, electron microscopy data, bulk chemistry data,

descriptions of the ore and minerals and other relevant information.<sup>322</sup> He also did extensive literature searches and reviewed the available peer-reviewed literature.<sup>323</sup> Dr. Krekeler also relied on published books regarding the geology of Vermont, Italy and China to the extent they were available, and other materials that geologists commonly rely on including the U.S. Geological Survey from the U.S. Bureau of Mines.<sup>324</sup> He used these methods and reliance materials which are generally accepted in the field of geology and would be expected if he was working as a consultant in a company reviewing a mine.<sup>325</sup> He also reviewed corporate documents and corporate deposition testimony.<sup>326</sup> Dr. Krekeler relied on his experience and methodology from both the academic and private sector in preparing his opinions.<sup>327</sup>

Dr. Cook also did extensive research and document review to compile his report. He reviewed published literature and corporate documents provided in the litigation.<sup>328</sup> He followed standard research methodology with the same attention to

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<sup>322</sup> See January 25, 2019 Deposition of Mark Krekeler, Ph.D. (“Krekeler Dep.”) at 324:2-11, attached hereto as **Exhibit 119**.

<sup>323</sup> *Id.* at 325:14; Krekeler Report at 2.

<sup>324</sup> Krekeler Dep. at 324:12-325:1.

<sup>325</sup> Krekeler Dep. at 324:9-11; 325:2-5.

<sup>326</sup> Krekeler Report at 2.

<sup>327</sup> *Id.* at 2

<sup>328</sup> See January 30, 2019 Deposition of Robert Cook, Ph.D. (“Cook Dep.”) at 456:1 to 458:5, attached hereto as **Exhibit 120**; Cook Report at 3, Cook Report Ex. B at 3.

detail he used as a professor of geology,<sup>329</sup> as well as the same methodology he practices as a consultant for mining companies.<sup>330</sup>

J&J claims that Drs. Krekeler and Cook improperly support their opinions with identical charts<sup>331</sup> assembled wholly by Plaintiffs' counsel. This ignores the testimony of both experts. Dr. Krekeler testified in his deposition that he reviewed documents, then selected certain documents for Plaintiffs' counsel to compile in a chart format.<sup>332</sup> Dr. Cook made it clear that the chart was composed of documents that he had seen, reviewed and summarized in narrative form. He testified that after he saw and digested the Hopkins chart he thought it would be better to present the results in a chart. While the attorneys for plaintiffs performed the clerical function of creating the chart, Dr. Cook checked it and states clearly that the documents were not new.<sup>333</sup> Both experts reviewed the documents and requested that charts be made. Rather than artificially create two separate charts based on the same documents, Plaintiffs' counsel compiled the data at the request of Drs. Krekeler and Cook. Both

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<sup>329</sup> Cook Dep. at 460:19 to 461:20

<sup>330</sup> Cook Dep. at 461:22 to 462:16

<sup>331</sup> These two charts include test results positive for asbestos and test results positive for fibrous talc.

<sup>332</sup> Krekeler Dep. at 40:6-41:14.

<sup>333</sup> Cook Dep. at 55:19 to 57:10; 57:18-57:24; 58:10-59:2; 60:3-60:8.

experts requested the creation of the charts, reviewed the underlying documents, reviewed the charts and contributed to the entries.

Using the charts as an example, J&J claims that Drs. Cook and Krekeler may not be used “as a mere vessel through which to funnel ‘information provided to her by a party.’”<sup>334</sup> However J&J cites *State Farm Fire & Cas. Co*<sup>335</sup> where an expert was excluded for doing an improper analysis and using data from “two difference sources rather than two comparable sources.”<sup>336</sup> The Court noted that the expert “had not confirmed that her analysis was comparing apples to apples rather than apples to oranges.”<sup>337</sup> Although the information had come from counsel, it was not excluded for that reason. Here, there is no comparable statistical comparison being made and while Counsel compiled the charts – that is all they did.

As the charts were used in their expert reports, J&J claims that Drs. Krekeler and Cook relied on counsels’ summary of the evidence. Nothing could be farther from the truth. J&J’s reliance on *Crowley v. Chait*<sup>338</sup> for the proposition that experts cannot rely on a summary of the record evidence prepared by a party’s counsel is

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<sup>334</sup> Def. Mem. at 94

<sup>335</sup> *State Farm Fire & Cas. Co v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031 (N.D. Ind. 2013).

<sup>336</sup> *Id.* at 1038.

<sup>337</sup> *Id.* at 1039.

<sup>338</sup> 322 F. Supp. 2d 530 (D.N.J. 2004).

misplaced. That case is distinguishable as the only evidence the expert relied on was a summary of 8 depositions out of 150 that were available. The court noted that the expert did little independent research and his conclusions were based on a highly filtered version of events. Here, Drs. Krekeler and Cook reviewed relevant literature and hundreds of (documents including geology analyses, reports, maps, core logs, test results, among other) and each wrote their own reports. These results are from documents that the experts reviewed and are included on their reliance lists. The chart was created so the court can easily see the information.<sup>339</sup>

**2. The materials relied upon by Drs. Cook and Krekeler support their reports and conclusions**

Drs. Cook and Krekeler both reviewed hundreds of documents.<sup>340</sup> Each expert did their own research including literature searches and reviewed corporate documents and deposition testimony.<sup>341</sup>

J&J argues that the counsel-selected documents on which Drs. Cook and Krekeler rely fail to furnish a reliable basis for their conclusions.<sup>342</sup> Yet, the only documents supplied by Counsel were requested by the experts. As all corporate documents are in Plaintiffs' counsel's custody, the only avenue to produce them is

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<sup>339</sup> Krekeler Dep. 40:6- 41:14; Cook Dep. at 55:19- 57:10.

<sup>340</sup> Cook Dep. at 457:23-458:5.

<sup>341</sup> Krekeler Dep. at 324:2-325:15; Cook Dep. at 456:1 to 458:5

<sup>342</sup> Def. Mem. at 96.

through counsel. Each expert requested certain types of documents and an expert's selection of scientific publications or other relevant materials for review goes to the weight of the expert's opinions and credibility, not the testimony's admissibility.<sup>343</sup> The opposing party can confront the expert on cross-examination and use their own experts to challenge the scope of the expert's review.<sup>344</sup> Even when an expert allegedly "ignores" studies or information that support a party's contrary position, "it is not the province of the court to choose between the competing theories when both are supported by reliable scientific evidence."<sup>345</sup> Dr. Krekeler could not independently obtain corporate documents, so all documents by necessity would be selected by counsel.<sup>346</sup> However, he requested and reviewed documents that he would have relied on in his normal course of his role as a geologist.<sup>347</sup> The same is true of Dr. Cook.

J&J goes through a number of sources claiming that each are not supportive of the experts' conclusions and therefore the entire report should be excluded. J&J

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<sup>343</sup> *In re Bair Hugger Forced Air Warming Devices Products Liability Litigation*, 2017 WL 6397721, at \*7 (D. Minn. Dec. 13, 2017).

<sup>344</sup> *Id.*

<sup>345</sup> *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 633 (8th Cir. 2012); *see also In re NuvaRing Prods. Liab. Litig.*, 2013 WL 791787, at \*2-3 (E.D. Mo. Mar. 4, 2013).

<sup>346</sup> Krekeler Dep. at 325:15-24.

<sup>347</sup> Krekeler Dep. at 325:24-326:16.

ignores the rest of the evidence relied upon by Drs. Cook and Krekeler for their opinions.

**3. J&J's efforts to cherry-pick Drs. Krekeler's and Cook's reliance materials are misleading**

Drs. Krekeler and Cook reviewed many documents related to the talc mines and testing of the ore and finished products. A few examples of documents and reports that involve other mines do not negate all the data from the mines that were used to source talc. Any mistakes in Drs. Krekeler and Cook's reports should be addressed in cross examination. "Indeed, federal courts have generally found that 'the perceived flaws' in an expert's testimony often should be treated as 'matters properly to be tested in the crucible of the adversarial system, 'not as 'the basis for truncating that process.'"<sup>348</sup>

In trying to use a few examples to exclude many other valid observations, J&J mischaracterizes the testimony from Plaintiffs' experts. For example, when claiming that Dr. Cook is citing studies and literature that are not specific to the mines used for J&J cosmetic talc products,<sup>349</sup> J&J ignores the fact that Dr. Cook considered these materials because they are relevant to the particular region's geology. Dr.

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<sup>348</sup> *Violas v. GMC*, 73 F.Supp 2d 452, 462 (D.N.J. 1999). (quoting *Walker v. Yellow Freigh Sys.,Inc.* 1999 U.S. Dist LEXIS 15012, No. CIV.A.98-3565, 1999 WL 757022, at \*8 (E.D.La Sept 24, 1999)).

<sup>349</sup> Def. Mem. at 98.

Cook cites a letter from Bill Ashton to the Colorado School of Mines regarding the Val Chisone Valley in Italy, which contains the Fontane Mine where J&J talc was mined.<sup>350</sup> He cites the letter to document the mineralization of the valley where the mine is located. The document speaks generally about the geology and does not exclude the mine's location from its analysis.<sup>351</sup> In addition to that letter, he cites numerous other references related to the Italian talc used for J&J's products that are not challenged, including Dr. Pooley's report from the University of Cardiff and multiple corporate documents.<sup>352</sup> Dr. Cook noted that the documents regarding the Val Chisone Valley was "general geologic information so that there was a foundation upon which the more detailed information could be anchored."<sup>353</sup>

J&J attempts to do the same thing with Dr. Cook's descriptions regarding Vermont. For example, J&J cites Dr. Cook's report<sup>354</sup> regarding Vermont to point out that various mines were not used for J&J's products. However, Dr. Cook was citing those mines to set "the stage for the geologic framework within which the ultramafic rocks occurred...they weren't intended to point out any character events,

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<sup>350</sup> Exhibit 20 to Cook Deposition.

<sup>351</sup> Cook Dep. at 246:22 to 249:23.

<sup>352</sup> See Cook Report at 10 for a section outlining the minerology in Italy and numerous corporate documents that discuss the asbestos and fibrous talc found in Italian talc.

<sup>353</sup> Cook Dep. at 458:14-459:3.

<sup>354</sup> Def. Mem. at 99 citing mines that are not where talc was sourced from.

any specific mines.”<sup>355</sup> His report notes “the talc deposits described in these publications occur as part of the same geological belt as the mines that sourced J&J’s Talcum Powder Products.”<sup>356</sup> He does not claim that J&J products were actually sourced from those mines. The same is true for Dr. Krekeler. His report discusses the Geological Survey that provides information on the Vermont mines and the Appalachian Ultramafic Belt.<sup>357</sup> He discusses information generally that describes the extensive geologic terrain that includes the talc mines.<sup>358</sup> Both experts gave background information and discussed regional geology and its application. Then they both looked at the specific mines with core logs, individual tests, analyses, etc. Documents reviewed included many core logs and maps<sup>359</sup> and various mine specific

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<sup>355</sup> Cook Dep. at 458:15-21.

<sup>356</sup> Cook Report at 11.

<sup>357</sup> Krekeler Report at 10.

<sup>358</sup> Krekeler Dep. at 315:10-316:6.

<sup>359</sup> A small set of examples include IMERYS 441340 at 441346, attached hereto as **Exhibit 121** (Maps of Ludlow Mines and data included in 2008 Annual Report for Mineral Resources and Ore Reserves Estimates, Argonaut Mine); IMERYS 427326 (core Logs), attached hereto as **Exhibit 122**; IMERYS 427419 (Core drill log, includes serpentinite), attached hereto as **Exhibit 123**; IMERYS 436951 (mine aerial pictures and ore description sheets), attached hereto as **Exhibit 124**; IMERYS 427428 (Core Drill Logs for south end of Argonaut mine), attached hereto as **Exhibit 125**; IMERYS 418940 (memo with Argonaut Geology Maps attached), attached hereto as **Exhibit 126**.

analyses.<sup>360</sup> Evidence from the separate talc deposits are relevant as they are geologically related.<sup>361</sup>

J&J cites to two fibrous talc results, one potentially from the Gouverneur Mine<sup>362</sup> and one potentially from the Gassett mine, as samples that were not from J&J mines.<sup>363</sup> Even if Plaintiffs concede these samples were included in error, there

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<sup>360</sup> Examples include Pltf\_IMERYYS\_00057875 (Downey Ex. 12, Memo re Cyprus Ore Reserves), attached hereto as **Exhibit 127**; Hopkins Exhibit 28 (chart of Samples with asbestos); IMERYYS 441340 (2008 Annual Report for Mineral Resources and Ore Reserves Estimates, Argonaut Mine); IMERYYS 501902 (Geology of and Product Applications for the Argonaut Talc Mine, Ludlow, Vermont), attached hereto as **Exhibit 128**; IMERYYS 238270 (1992 Interoffice Memo re Hamm Mine Core Drilling fibrous amphiboles observed), attached hereto as **Exhibit 129**; IMERYYS 418940 (Mineralogy Analysis of Vermont includes report on Tremolite asbestos in Vermont talc), attached hereto as **Exhibit 130**; IMERYYS 425354 (Cyprus Ore Reserve Evaluation, Preliminary Summary by R.C. Munro noting fibrous actinolite and fibrous tremolite in J&J mines), attached hereto as **Exhibit 131**; IMERYYS 427291 (North American Mines, Northeastern Ore Bodies, Master Plan, notes actinolite zones), attached hereto as **Exhibit 132**; IMERYYS 427326 (Argonaut Core Logs), attached hereto as **Exhibit 133**; IMERYYS 435992 (Hamm Mine Drill log showing fibrous tremolite), attached hereto as **Exhibit 134**; IMERYYS 436000 (Hamm Mine Drill Log showing fibrous actinolite), attached hereto as **Exhibit 135**; JNJ 000245002 (Hammondsville Geology and Ore Reserves, showing fibrous talc).

<sup>361</sup> Krekeler Dep. at 195:22-196:4; 200:3014.

<sup>362</sup> The documents used by Drs. Krekeler and Cook do not identify the talc as from the Gouverneur Mine. *See* JNJ 000238826; JNJ 000248023, attached hereto as **Exhibits 136 and 137**. Instead, J&J had to take Dr. Cook through multiple documents to try to prove this. Cook Dep. 388:21-393:20.

<sup>363</sup> Def. Mem. at 99-100.

are still 39 out of 41 positive tests left for the talc. This mistake does not undermine the credibility and relevance of the other positive samples.<sup>364</sup>

J&J also complains that Drs. Krekeler and Cook rely on reports and testing of non-ore mineral specimens. To prove this J&J relies on its own expert's testimony.<sup>365</sup> Generally, when there are different interpretations that can be given to data you have a "classic battle of the experts, a battle in which the jury must decide the victor."<sup>366</sup> The Pooley Report that tests Italian Talc is used as an example of a document that tested non-talc mineral inclusions.<sup>367</sup> However, while some of the samples were not talc ore, there are numerous samples that specifically state they are including I.18, I.19, I.39, and I.41.<sup>368</sup> The I.41 description identifies it as a "specimen of talc ore" and notes that it "occasionally contain long prismatic inclusions of

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<sup>364</sup> J&J also attempts to do this with the asbestos brief looking at samples that may have come from the Red Hill Mine and the Frostbite Mine. Again, if Plaintiffs concede these two instances as mistakes, then there are over 100 positive results left in the chart showing asbestos results.

<sup>365</sup> Def. Mem. at 101.

<sup>366</sup> *Lanzilotti v. Merrell Dow Pharms.*, 1986 U.S. Dist. LEXIS 23047, 1986 WL 7832 (E.D. Pa. 1986) (quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C.Cir. 1984)).

<sup>367</sup> Def. Mem. at 101.

<sup>368</sup> See JNJ 000322351, attached hereto as **Exhibit 138**.

tremolite” which Dr. Cook notes in his report is suggestive of fibrous or asbestiform minerals.<sup>369</sup>

**4. Drs. Krekeler and Cook properly rely on test results indicating the presence of asbestos**

Both Drs. Krekeler and Cook describe asbestiform and non-asbestiform minerals in their reports.<sup>370</sup> While J&J may point to examples of talc test results that only list “tremolite” without distinguishing between the forms, there are others that describe the fibers and indicate it is asbestiform. In Dr. Cook’s report, before the asbestos chart, he notes that it includes “serpentine asbestos (chrysotile), amphibole asbestos, or potentially asbestiform amphiboles.” Anything that is “potentially asbestiform” is something for the jury to consider and can be attacked on cross-examination.<sup>371</sup> Both reports give examples of results that are clearly asbestos including chrysotile, asbestos fibers, fibrous minerals and other descriptions.<sup>372</sup>

**5. Dr. Krekeler’s testimony regarding cleavage fragments**

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<sup>369</sup> Cook Report at 10. *See also* JNJ 000322351 sample I.19 which notes that the sample includes “crystal aggregates of tremolite associated with minor amounts of fine fibrous talc.”

<sup>370</sup> Krekeler Report at 4, Cook Report at 4.

<sup>371</sup> *Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”)

<sup>372</sup> *See* Cook Report and Krekeler Report.

One of the common threads in the Defense Expert reports is the distinction between cleavage fragments and asbestos. J&J's expert Dr. Dyar claims that every sample Dr. Longo reviewed that he said was asbestos fibers or asbestos bundles with PLM are actually cleavage fragments.<sup>373</sup> So, the argument between cleavage fragments and asbestos is an area ripe for disagreement and should be presented to a jury. Further, J&J claim that there is no evidence to support any changing of non-asbestiform particles into asbestiform particles. This was discussed during Dr. Krekeler's deposition.<sup>374</sup> He stated that to be asbestos it has to meet the definition of asbestos including particle size and mineralogy,<sup>375</sup> which holds true regardless of his theoretical discussion in his deposition. The United States Supreme Court has recognized that there is a range in which experts might reasonably differ on issues of science, and that such conflicting evidence should be admitted to aid the jury in deciding those issues.<sup>376</sup>

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<sup>373</sup> Dyar Dep. at 291:13-24.

<sup>374</sup> Krekeler Dep. at 77:20-78:11.

<sup>375</sup> Krekeler Dep. at 104:16-22.

<sup>376</sup> *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 1953 (1999); *Ambrosini v. Labarraque*, 101 F.3d 129, 138-139 (D.C. Cir. 1996) ("there is nothing in Daubert to suggest that judges become scientific experts, must less evaluators of the persuasiveness of an expert's conclusion"); *Globetti v. Sandoz Pharm. Corp.*, 111 F.Supp. 2d 1174, 1176 (N.D. Ala. 2000) (role of fact finder, not judge, is to decide whether opinion is correct or worthy of credence).

J&J also criticizes Dr. Krekeler's opinions related to health effects.<sup>377</sup> Dr. Krekeler is not giving causation opinions related to asbestos, talc or any of the possible contaminants. However, minerals, their properties and the levels that are safe for humans are included in his experience and training. J&J insinuates that Dr. Krekeler oversteps the bounds of his qualifications when he opines that non-asbestiform cleavage fragments are similar to asbestos and pose the same risks to human health. J&J yet again misrepresents both the words and intent of Dr. Krekeler's testimony. Dr. Krekeler is a mineralogist, and as such concentrates on the geology and formation of minerals found within the earth's crust. Professionally, he instructs students on the benefits and risks of these minerals' extraction and use in various applications they may encounter in their own careers as geologists and mineralogists. Part of this instruction necessarily involves knowing whether these minerals, in any form, may have carcinogenic properties. His statements regarding carcinogens and health effects were not intended as a health-related opinions in this matter, but as statements of fact learned throughout his education and training.

#### **IV. CONCLUSION**

In reaching their opinions, the PSC's experts—not J&J—employed accepted definitions of asbestos and appropriate scientific methodologies in determining that J&J's Talcum Powder Products contained asbestos. The link between asbestos and

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<sup>377</sup> Def. Mem. at 104-109.

ovarian cancer is fully established in the scientific literature. Finally, there is ample evidence in the record establishing the presence of asbestos in the source mines J&J utilized. For all the foregoing reasons, this Court should deny J&J's Motion to Exclude Plaintiffs' Experts' Asbestos Related Opinions.

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